Coronary Computed Tomography Angiography With Selective Noninvasive Fractional Flow Reserve

Policy # 00537
Original Effective Date: 02/15/2017
Current Effective Date: 10/20/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Contrast-Enhanced Coronary Computed Tomography Angiography (CCTA) for Coronary Artery Evaluation is addressed in medical policy 00153.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the use of noninvasive fractional flow reserve (FFR) following a positive coronary computed tomography angiography (CCTA) to guide decisions about the use of invasive coronary angiography (ICA) to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility may be considered for the use of noninvasive fractional flow reserve (FFR) following a positive coronary computed tomography angiography (CCTA) to guide decisions about the use of invasive coronary angiography (ICA) when **ALL** of the following criteria are met:

- The patient has symptoms consistent with myocardial ischemia; **AND**
- Symptoms persist despite maximal guideline-directed medical therapy (see Policy Guidelines); **AND**
- CCTA has been performed in the preceding 90 days; **AND**
- There is at least one 40%-90% coronary stenosis located in the proximal or middle segment of a major native coronary artery or a named branch thereof.

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

The use of noninvasive fractional flow reserve (FFR) not meeting the criteria outlined above is considered to be **investigational.***

Policy Guidelines

Fractional flow reserve using coronary computed tomography angiography requires at least 64-slice coronary computed tomography angiography and cannot be calculated when images lack sufficient quality (11% to 13% in recent studies; e.g., in obese individuals [body mass index, >35 kg/m2]). The presence of dense arterial calcification or an intracoronary stent can produce significant beam-hardening 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.

Guideline-directed medical therapy (GDMT) consists of risk factor management and, in symptomatic patients, antianginal medications which improve quality of life.

Risk factor management:
All patients with stable CAD should be encouraged to adopt healthy lifestyles including tobacco cessation/avoidance, regular physical activity, maintenance of a healthy weight and adherence to a healthy diet. In addition, absent a contraindication, all stable CAD patients should be taking the following evidence-supported medications:

- Antiplatelet agents – Aspirin and/or P2Y12 receptor antagonist
- Statin – Maximum tolerated dose of high-intensity statin (atorvastatin 40-80 mg or rosuvastatin 20-40 mg). Patients intolerant of statins and/or not reaching LDL cholesterol goal on maximum tolerated statin dose should be treated with ezetimibe, a PCSK9 inhibitor, or bempedoic acid.
- Beta blockers – In patients with a history of myocardial infarction, who have left ventricular

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systolic dysfunction (ejection fraction ≤ 40%), or as an option for management of hypertension.
- ACE Inhibitor or Angiotensin Receptor Blocker – In patients with left ventricular systolic dysfunction (ejection fraction ≤ 40%), diabetes, chronic kidney disease, or as an option for management of hypertension
- Antidiabetic agents – For patients who are diabetic (Hemoglobin A1c goal should be < 8% in all patients although more aggressive management may be appropriate for some)

Symptom control:
Most patients with stable CAD who have symptoms should be offered anti anginal medications as an initial approach with revascularization reserved for those who have persistent unacceptable symptoms despite maximally tolerated doses.
- Beta blockers – Unless contraindicated beta blockers are first-line therapy with dose escalation until symptoms resolve or side effects develop.
- Calcium channel blockers and/or long acting-nitrates should be used as alternative initial therapy in symptomatic patients who have contraindication to, or intolerance of, beta blockers. They should also be prescribed when symptoms persist despite maximum tolerated doses of beta blockers.
- Ranolazine may be prescribed either as initial therapy in symptomatic patients who have contraindication to, or intolerance of, other antianginal medication, or for those with persistent symptoms despite treatment with other medications as described above.

Background/Overview

Stable Ischemic Heart Disease
Coronary artery disease (CAD) is a significant cause of morbidity and mortality. Various epidemiologic risk factors have been well studied. Evaluation of obstructive CAD involves quantifying arterial stenoses 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 (ICA) in patients with a low clinical likelihood of significant CAD. However, ICA is frequently unnecessary in patients with suspected stable ischemic heart disease, as evidenced by low

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diagnostic yields for significant obstructive CAD. Patel et al (2010) found that from a sample of over 132,000 ICAs, 48.8% of elective ICAs performed in patients with stable angina did not detect obstructive CAD (left main stenosis ≥50% or ≥70% in a major epicardial or branch >2.0 mm in diameter). Invasive coronary angiography is clinically useful when patients with stable angina have failed optimal medical therapy and may benefit from revascularization. A noninvasive imaging test performed before ICA as a gatekeeper, which can distinguish candidates who may benefit from early revascularization (eg, patients with unprotected left main stenosis ≥50% or hemodynamically significant disease) from those unlikely to benefit, could avoid unnecessary invasive procedures and their potential adverse consequences. Moreover, for the large majority of patients with stable ischemic heart disease, revascularization offers no survival advantage over medical therapy; few might benefit from ICA if they have not first failed optimal medical therapy.

Clinical Risk Prediction for Stable Ischemic Heart Disease

A 2012 collaborative medical association guideline for the diagnosis and management of patients with stable heart disease lists several class I recommendations on the use of noninvasive testing in patients with suspected stable ischemic heart disease. A class I recommendation indicates that a test should be performed. In general, patients with at least intermediate risk (10% to 90% risk by standard risk prediction instruments) are recommended to have some type of test, the choice depending on the interpretability of the electrocardiogram, the capacity to exercise, and the presence of comorbidity. In 2023, an updated collaborative medical association guideline for patients with chronic coronary disease was published to provide an update to and consolidate new evidence since the 2012 guideline for the diagnosis and management of patients with stable heart disease and the corresponding 2014 focused update of the guideline for the diagnosis and management of patients with stable ischemic heart disease. A class 1 recommendation states that "in patients with chronic coronary disease, it is recommended that risk stratification incorporate all available information, including noninvasive, invasive, or both cardiovascular diagnostic testing results or use validated risk scores to classify patients as low (<1%), intermediate (1%-3%), or high (>3%) yearly risk for cardiovascular death or nonfatal myocardial infarction." The text further states that noninvasive test results alone are insufficient to adequately risk stratify patients with chronic coronary disease, and the additional information improves risk prediction.

Clinical prediction scores or models have been developed to help estimate the pretest probability of CAD in individuals with stable chest pain. Diamond and Forrester (1979) developed the original

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version of a commonly cited clinical prediction model based on age, sex, and type of pain symptoms. X Versteylen et al (2011) published a comparison of clinical prediction results for the Diamond and Forrester (1979) model, the Framingham risk score, the PROCAM risk score, and the SCORE risk estimation model. Min et al (2015) published another model, and in 2016 a CAD consortium developed an online calculator.

Gatekeepers to Invasive Coronary Angiography

Imposing an effective noninvasive gatekeeper strategy with one or more tests before planned ICA to avoid unnecessary procedures is compelling. The most important characteristic of a gatekeeper test is its ability to accurately identify and exclude clinically insignificant disease where revascularization would offer no potential benefit. From a diagnostic perspective, an optimal strategy would result in few false-negative tests while avoiding an excessive false-positive rate—it would provide a low post-test probability of significant disease. Such a test would then have a small and precise negative likelihood ratio and high negative predictive value. An effective gatekeeper would decrease the rate of ICA while increasing the diagnostic yield (defined by the presence of obstructive CAD on ICA). At the same time, there should be no increase in major adverse cardiac events (MACE). A clinically useful strategy would satisfy these diagnostic performance characteristics and impact the outcomes of interest. Various tests have been proposed as potentially appropriate for a gatekeeper function before planned ICA, including CCTA, magnetic resonance imaging, single-photon emission computed tomography, positron emission tomography, and stress echocardiography. More recently, adding noninvasive measurement of fractional flow reserve using CCTA has been suggested, combining functional and anatomic information.

Fractional Flow Reserve

Invasively measured fractional flow reserve evaluates the severity of ischemia caused by coronary artery obstructions and can predict when revascularization may be beneficial. Fractional flow reserve has not been used as a diagnostic test for ischemic heart disease, but as a test to evaluate the degree of ischemia caused by stenosis.

Invasive fractional flow reserve is rarely used in the U.S. to guide percutaneous coronary intervention (PCI). Pothineni et al (2016), using the National Inpatient Sample, reported that 201,705 PCIs were performed in 2012, but just 21,365 fractional flow reserve procedures. Assuming the intention of fractional flow reserve is to guide PCI, it would represent just 4.3% of PCI procedures.

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Whether noninvasively obtained fractional flow reserve will influence decisions concerning ICA, over and above anatomic considerations, is therefore important to establish empirically.

Randomized controlled trials and observational studies have demonstrated that fractional flow reserve-guided revascularization can improve cardiovascular outcomes, reduce revascularizations, and decrease costs. For example, the Fractional Flow Reserve versus Angiography for Multivessel Evaluation trial randomized 1005 patients with multivessel disease and planned PCI. At 1 year, compared with PCI guided by angiography alone, fractional flow reserve-guided PCI reduced the number of stents placed by approximately 30%, followed by lower rates (13.2% vs. 18.3%) of MACE (myocardial infarction, death, repeat revascularization) and at a lower cost. The clinical benefit persisted through 2 years, although by 5 years, event rates were similar between groups.

European guidelines (2013) for stable CAD have recommended that fractional flow reserve be used "to identify hemodynamically relevant coronary lesion(s) when evidence of ischaemia is not available" (class Ia), and "[r]evascularization of stenoses with fractional flow reserve <0.80 is recommended for patients with angina symptoms or a positive stress test." A 2019 European guideline on chronic coronary syndromes recommends to "consider revascularization on top of medical therapy" in patients without evidence of ischaemia but with fractional flow reserve ≤0.80. Other guidelines (2014) have recommended using "fractional flow reserve to identify haemodynamically relevant coronary lesion(s) in stable patients when evidence of ischaemia is not available" (class Ia recommendation). The U.S. guidelines (2012) have stated that a fractional flow reserve of ≤0.80 provides level Ia evidence for revascularization for "significant stenoses amenable to revascularization and unacceptable angina despite guideline directed medical therapy." A 2023 U.S guideline for patients with chronic coronary disease notes the following for patients with fractional flow reserve of 0.80 or less: "consideration of revascularization, antianginal therapy as per guidelines." Also, the importance of fractional flow reserve in decision making appears prominently in the 2017 appropriate use criteria for coronary revascularization in patients with stable ischemic heart disease.

Measuring fractional flow reserve during 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. Fractional flow reserve is the ratio of flow in the presence of a stenosis to flow in its absence. Fractional flow reserve levels less

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than 0.75 to 0.80 are considered to represent significant ischemia while those 0.94 to 1.0 are considered normal. Measurement is valid in the presence of serial stenoses, 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 fractional flow reserve during a typical ICA is less than 10 minutes.

Fractional flow reserve using CCTA requires at least 64-slice CCTA and cannot be calculated when images lack sufficient quality (11% to 13% in recent studies, eg, in obese individuals [body mass index, >35 kg/m^2]). The presence of dense arterial calcification or an intracoronary stent can produce significant beam-hardening 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 the 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 Fractional Flow Reserve Measurement
Fractional flow reserve can be modeled noninvasively using images obtained during CCTA (HeartFlow software termed FFR_{CT}; Siemens cFFR). The process involves constructing a digital model of coronary anatomy and calculating fractional flow reserve across the entire vascular tree using computational fluid dynamics. Fractional flow reserve using CCTA can also be used for "virtual stenting" to simulate how stent placement would be predicted to improve vessel flow.

Only HeartFlow FFR_{CT} software has been cleared by the U.S. Food and Drug Administration (FDA). Imaging analyses require uploading data to a cloud for analysis, taking as little as 5 hours to complete. Other prototype software developed by Siemens is workstation-based with onsite analyses.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
In November 2014, FFRCT simulation software (HeartFlow) was cleared for marketing by the 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.

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HeartFlow FFRCT 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 fractional flow reserve using coronary computed tomography angiography, 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. Fractional flow reserve using coronary computed tomography angiography analysis is intended to support the functional evaluation of coronary artery disease. The results of this analysis [FFRCT] are provided to support qualified clinicians to aid in the evaluation and assessment of coronary arteries. The results of HeartFlow fractional flow reserve using coronary computed tomography angiography 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."

In April 2022, DeepVessel®‡ FFR software (Keya Medical) received FDA approval through the 510(k) process.

DeepVessel FFR software is cleared:

> "for the clinical quantitative and qualitative analysis of previously acquired Computed Tomography [CT] DICOM data for clinically stable symptomatic patients with coronary artery disease. It provides DVFFR (a CT-derived FFR measurement) computed from static coronary CTA images using deep learning neural networks that encode imaging, structural, and functional characteristics of coronary arteries through learning. DEEPVESSEL FFR analysis is intended to support the functional evaluation of coronary artery disease. The results of the analysis are provided to support qualified clinicians to aid in the evaluation and assessment of coronary arteries. DEEPVESSEL FFR results are intended to be used by qualified clinicians in conjunction with the with the patient’s clinical history, symptoms, and other diagnostic tests, as well as the clinician’s professional judgment."

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Description

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

Summary of Evidence

For individuals with stable chest pain at intermediate risk of coronary artery disease (CAD) (ie, suspected or presumed stable ischemic heart disease) being considered for invasive coronary angiography (ICA) who receive noninvasive fractional flow reserve measurement following positive coronary computed tomography angiography (CCTA), the evidence includes both direct and indirect evidence: 4 meta-analyses on diagnostic performance; 1 prospective, multi-center, nonrandomized comparative study; 2 prospective, multi-center, randomized comparative studies; 4 prospective cohort studies; 5 retrospective cohort studies; and 1 study reporting changes in management associated with CCTA-based strategies with selective addition of fractional flow reserve using CCTA. Relevant outcomes are test accuracy and validity, morbid events, quality of life, resource utilization, and treatment-related morbidity. The meta-analyses indicated that CCTA has high sensitivity but moderately low specificity for hemodynamically significant obstructive disease. There is direct evidence that compares health outcomes observed during 90-day to 2-year follow-up for strategies using CCTA (particularly in combination with selective fractional flow reserve measurement) with strategies using ICA or other noninvasive imaging tests. The available evidence provides support that use of CCTA with selective fractional flow reserve measurement using CCTA is likely to reduce the use of ICA in individuals with stable chest pain who are unlikely to benefit

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from revascularization by demonstrating the absence of functionally significant obstructive CAD. Also, 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 fractional flow reserve measurement using CCTA strategy. Moreover, given the available evidence that CCTA alone has been used to select patients to avoid ICA, the studies showing higher specificity of fractional flow reserve measurement using CCTA and lower negative likelihood ratio of fractional flow reserve measurement using CCTA compared with CCTA alone may be used to build a chain of evidence that CCTA with a selective fractional flow reserve measurement using CCTA strategy would likely lead to changes in management that would be expected to improve health outcomes by further limiting unnecessary ICA testing. 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 fractional flow reserve measurement following CCTA results in an improvement in the net health outcome. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Heart Association, et al

In 2021, the American Heart Association, American College of Cardiology, American Society of Echocardiography, American College of Chest Physicians, Society for Academic Emergency Medicine, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance released a clinical practice guideline for the evaluation and diagnosis of chest pain. The guideline states that for "intermediate-risk patients with acute chest pain and no known coronary artery disease (CAD), with a coronary artery stenosis of 40% to 90% in a proximal or middle coronary artery on coronary computed tomography angiography (CCTA), fractional flow

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reserve with computed tomography can be useful for the diagnosis of vessel-specific ischemia and to guide decision-making regarding the use of coronary revascularization (class of recommendation [COR]: 2a (moderate; benefit >> risk); level of evidence [LOE]: B-NR (moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies or meta-analyses of such studies)." This recommendation also applies to those intermediate-risk patients with acute chest pain and known CAD (COR: 2a; LOE: B-NR).

National Institute for Health and Care Excellence
In 2017, NICE endorsed fractional flow reserve using CCTA, with the following conclusions: "The committee concluded that the evidence suggests that HeartFlow FFR_{CT} is safe, has high diagnostic accuracy, and that its use may avoid the need for invasive investigations."
Recommendations included:

- "The case for adopting HeartFlow FFR_{CT} for estimating fractional flow reserve from CCTA is supported by the evidence. The technology is non-invasive and safe, and has a high level of diagnostic accuracy."
- "HeartFlow FFR_{CT} should be considered as an option for patients with stable, recent onset chest pain who are offered CCTA in line with the NICE guideline on chest pain. Using HeartFlow FFR_{CT} may avoid the need for invasive coronary angiography and revascularization. For correct use, HeartFlow FFR_{CT} requires access to 64-slice (or above) CCTA facilities."

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
In January 2018, the Centers for Medicare & Medicaid Services assigned a new technology ambulatory payment classification to HeartFlow, making Medicare-enrolled hospitals eligible for reimbursement for the technology.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 1.

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Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05174247	Addition of FFRct in the Diagnostic Pathway of Patients With Stable Chest Pain to Reduce Unnecessary Invasive Coronary Angiography	528	Apr 2025
NCT04939207	Improving the Cost-effectiveness Of Coronary Artery Disease Diagnosis	825	Apr 2025
NCT02208388	Prospective Evaluation of MyocaRdial PerFUSion ComputEd Tomography Trial: Ischemia-guided Revascularization Using Perfusion Coronary CT vs. Fractional Flow Reserve	1000	Mar 2028
NCT03329469	The Value of Fractional Flow Reserve Derived From Coronary CT Angiography as Compared to CCTA or CCTA and Stress MPI in the Triage of Low to Intermediate Emergent Chest Pain Patients With Toshiba CT-FFR	1142	Mar 2024
Unknown status			
NCT02973126	Assessment of Fractional Flow reservE Computed Tomography Versus Single Photon Emission Computed Tomography in the Diagnosis of Hemodynamically Significant Coronary Artery Disease. (AFFECTS)	270	July 2022
NCT04142021	A Multicenter, Pilot Study to Evaluate Safety and Feasibility Evaluation of Planning and Execution of Surgical Revascularization Solely Based on Coronary CTA and FFRCT in Patients With	114	Dec 2022

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NCT No.	Trial Name	Planned Enrollment	Completion Date
	Complex Coronary Artery Disease (FASTTRACK CABG)		

NCT: national clinical trial.

References

1. Carelon Medical Benefits Management, Clinical Appropriateness Guidelines, Advanced Imaging: Imaging of the Heart, "Coronary CT Angiography (CCTA) and CT Derived Fractional Flow Reserve (FFR-CT)", April 14, 2024.
2. Patel MR, Peterson ED, Dai D, et al. Low diagnostic yield of elective coronary angiography. N Engl J Med. Mar 11 2010; 362(10): 886-95. PMID 20220183
3. Boden WE, O'Rourke RA, Teo KK, et al. Optimal medical therapy with or without PCI for stable coronary disease. N Engl J Med. Apr 12 2007; 356(15): 1503-16. PMID 17387127
4. Fihn SD, Gardin JM, Abrams J, et al. 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for the diagnosis and management of patients with stable ischemic heart disease: a report of the 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. J Am Coll Cardiol. Dec 18 2012; 60(24): e44-e164. PMID 23182125
5. Virani SS, Newby LK, Arnold SV, et al. 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA Guideline for the Management of Patients With Chronic Coronary Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. Circulation. Aug 29 2023; 148(9): e9-e119. PMID 37471501
6. Diamond GA, Forrester JS. Analysis of probability as an aid in the clinical diagnosis of coronary-artery disease. N Engl J Med. Jun 14 1979; 300(24): 1350-8. PMID 440357
7. Wasfy MM, Brady TJ, Abbara S, et al. Comparison of the Diamond-Forrester method and Duke Clinical Score to predict obstructive coronary artery disease by computed tomographic angiography. Am J Cardiol. Apr 01 2012; 109(7): 998-1004. PMID 22236462

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8. Versteylen MO, Joosen IA, Shaw LJ, et al. Comparison of Framingham, PROCAM, SCORE, and Diamond Forrester to predict coronary atherosclerosis and cardiovascular events. J Nucl Cardiol. Oct 2011; 18(5): 904-11. PMID 21769703
9. Min JK, Dunning A, Gransar H, et al. Medical history for prognostic risk assessment and diagnosis of stable patients with suspected coronary artery disease. Am J Med. Aug 2015; 128(8): 871-8. PMID 25865923
10. Genders TS, Steyerberg EW, Hunink MG, et al. Prediction model to estimate presence of coronary artery disease: retrospective pooled analysis of existing cohorts. BMJ. Jun 12 2012; 344: e3485. PMID 22692650
11. CAD Consortium. Pre-test probability of CAD. 2016; https://www.qxmd.com/calculate/calculator_287/pre-test- probability-of-cad-cad-consortium.
12. De Bruyne B, Fearon WF, Pijls NH, et al. Fractional flow reserve-guided PCI for stable coronary artery disease. N Engl J Med. Sep 25 2014; 371(13): 1208-17. PMID 25176289
13. De Bruyne B, Pijls NH, Kalesan B, et al. Fractional flow reserve-guided PCI versus medical therapy in stable coronary disease. N Engl J Med. Sep 13 2012; 367(11): 991-1001. PMID 22924638
14. Tonino PA, De Bruyne B, Pijls NH, et al. Fractional flow reserve versus angiography for guiding percutaneous coronary intervention. N Engl J Med. Jan 15 2009; 360(3): 213-24. PMID 19144937
15. Pothineni NV, Shah NN, Rochlani Y, et al. U.S. Trends in Inpatient Utilization of Fractional Flow Reserve and Percutaneous Coronary Intervention. J Am Coll Cardiol. Feb 16 2016; 67(6): 732-733. PMID 26868697
16. Fearon WF, Shilane D, Pijls NH, et al. Cost-effectiveness of percutaneous coronary intervention in patients with stable coronary artery disease and abnormal fractional flow reserve. Circulation. Sep 17 2013; 128(12): 1335-40. PMID 23946263
17. van Nunen LX, Zimmermann FM, Tonino PA, et al. Fractional flow reserve versus angiography for guidance of PCI in patients with multivessel coronary artery disease (FAME): 5-year follow-up of a randomised controlled trial. Lancet. Nov 07 2015; 386(10006): 1853-60. PMID 26333474
18. Montalescot G, Sechtem U, Achenbach S, et al. 2013 ESC guidelines on the management of stable coronary artery disease: the Task Force on the management of stable coronary artery disease of the European Society of Cardiology. Eur Heart J. Oct 2013; 34(38): 2949-3003. PMID 23996286

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19. Knuuti J, Wijns W, Saraste A, et al. 2019 ESC Guidelines for the diagnosis and management of chronic coronary syndromes. Eur Heart J. Jan 14 2020; 41(3): 407-477. PMID 31504439
20. Windecker S, Kolh P, Alfonso F, et al. 2014 ESC/EACTS Guidelines on myocardial revascularization: The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)Developed with the special contribution of the European Association of Percutaneous Cardiovascular Interventions (EAPCI). Eur Heart J. Oct 01 2014; 35(37): 2541-619. PMID 25173339
21. Patel MR, Calhoon JH, Dehmer GJ, et al. ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/STS 2017 Appropriate Use Criteria for Coronary Revascularization in Patients With Stable Ischemic Heart Disease: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society of Thoracic Surgeons. J Am Coll Cardiol. May 02 2017; 69(17): 2212-2241. PMID 28291663
22. Pijls NH, Van Gelder B, Van der Voort P, et al. Fractional flow reserve. A useful index to evaluate the influence of an epicardial coronary stenosis on myocardial blood flow. Circulation. Dec 01 1995; 92(11): 3183-93. PMID 7586302
23. de Bruyne B, Bartunek J, Sys SU, et al. Simultaneous coronary pressure and flow velocity measurements in humans. Feasibility, reproducibility, and hemodynamic dependence of coronary flow velocity reserve, hyperemic flow versus pressure slope index, and fractional flow reserve. Circulation. Oct 15 1996; 94(8): 1842-9. PMID 8873658
24. HeartFlow. De Novo Classification Request for FFRct v. 1.4. 2013; https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN130045.pdf.
25. Koo BK, Erglis A, Doh JH, et al. Diagnosis of ischemia-causing coronary stenoses by noninvasive fractional flow reserve computed from coronary computed tomographic angiograms. Results from the prospective multicenter DISCOVER-FLOW (Diagnosis of Ischemia-Causing Stenoses Obtained Via Noninvasive Fractional Flow Reserve) study. J Am Coll Cardiol. Nov 01 2011; 58(19): 1989-97. PMID 22032711
26. Min JK, Koo BK, Erglis A, et al. Effect of image quality on diagnostic accuracy of noninvasive fractional flow reserve: results from the prospective multicenter international DISCOVER-FLOW study. J Cardiovasc Comput Tomogr. 2012; 6(3): 191-9. PMID 22682261

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27. Nakazato R, Park HB, Berman DS, et al. Noninvasive fractional flow reserve derived from computed tomography angiography for coronary lesions of intermediate stenosis severity: results from the DeFACTO study. Circ Cardiovasc Imaging. Nov 2013; 6(6): 881-9. PMID 24081777
28. Nørgaard BL, Leipsic J, Gaur S, et al. Diagnostic performance of noninvasive fractional flow reserve derived from coronary computed tomography angiography in suspected coronary artery disease: the NXT trial (Analysis of Coronary Blood Flow Using CT Angiography: Next Steps). J Am Coll Cardiol. Apr 01 2014; 63(12): 1145-1155. PMID 24486266
29. Taylor CA, Fonte TA, Min JK. Computational fluid dynamics applied to cardiac computed tomography for noninvasive quantification of fractional flow reserve: scientific basis. J Am Coll Cardiol. Jun 04 2013; 61(22): 2233-41. PMID 23562923
30. Kim KH, Doh JH, Koo BK, et al. A novel noninvasive technology for treatment planning using virtual coronary stenting and computed tomography-derived computed fractional flow reserve. JACC Cardiovasc Interv. Jan 2014; 7(1): 72-8. PMID 24332418
31. Pontone G, Guaricci AI, Palmer SC, et al. Diagnostic performance of non-invasive imaging for stable coronary artery disease: A meta-analysis. Int J Cardiol. Feb 01 2020; 300: 276-281. PMID 31748186
32. Wu W, Pan DR, Foin N, et al. Noninvasive fractional flow reserve derived from coronary computed tomography angiography for identification of ischemic lesions: a systematic review and meta-analysis. Sci Rep. Jul 05 2016; 6: 29409. PMID 27377422
33. Danad I, Szymonifka J, Twisk JWR, et al. Diagnostic performance of cardiac imaging methods to diagnose ischaemia-causing coronary artery disease when directly compared with fractional flow reserve as a reference standard: a meta-analysis. Eur Heart J. Apr 01 2017; 38(13): 991-998. PMID 27141095
34. Renker M, Schoepf UJ, Wang R, et al. Comparison of diagnostic value of a novel noninvasive coronary computed tomography angiography method versus standard coronary angiography for assessing fractional flow reserve. Am J Cardiol. Nov 01 2014; 114(9): 1303-8. PMID 25205628
35. De Geer J, Sandstedt M, Björkholm A, et al. Software-based on-site estimation of fractional flow reserve using standard coronary CT angiography data. Acta Radiol. Oct 2016; 57(10): 1186-92. PMID 26691914
36. Wardziak Ł, Kruk M, Pleban W, et al. Coronary CTA enhanced with CTA based FFR analysis provides higher diagnostic value than invasive coronary angiography in patients with intermediate coronary stenosis. J Cardiovasc Comput Tomogr. 2019; 13(1): 62-67. PMID 30309764

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37. Min JK, Leipsic J, Pencina MJ, et al. Diagnostic accuracy of fractional flow reserve from anatomic CT angiography. JAMA. Sep 26 2012; 308(12): 1237-45. PMID 22922562
38. Thompson AG, Raju R, Blanke P, et al. Diagnostic accuracy and discrimination of ischemia by fractional flow reserve CT using a clinical use rule: results from the Determination of Fractional Flow Reserve by Anatomic Computed Tomographic Angiography study. J Cardiovasc Comput Tomogr. 2015; 9(2): 120-8. PMID 25819194
39. Whiting PF, Rutjes AW, Westwood ME, et al. QUADAS-2: a revised tool for the quality assessment of diagnostic accuracy studies. Ann Intern Med. Oct 18 2011; 155(8): 529-36. PMID 22007046
40. Coenen A, Lubbers MM, Kurata A, et al. Fractional flow reserve computed from noninvasive CT angiography data: diagnostic performance of an on-site clinician-operated computational fluid dynamics algorithm. Radiology. Mar 2015; 274(3): 674-83. PMID 25322342
41. An Z, Tian J, Zhao X, et al. Machine Learning-Based CT Angiography-Derived Fractional Flow Reserve for Diagnosis of Functionally Significant Coronary Artery Disease. JACC Cardiovasc Imaging. Mar 2023; 16(3): 401-404. PMID 36889853
42. Douglas PS, De Bruyne B, Pontone G, et al. 1-Year Outcomes of FFRCT-Guided Care in Patients With Suspected Coronary Disease: The PLATFORM Study. J Am Coll Cardiol. Aug 02 2016; 68(5): 435-445. PMID 27470449
43. Douglas PS, Pontone G, Hlatky MA, et al. Clinical outcomes of fractional flow reserve by computed tomographic angiography-guided diagnostic strategies vs. usual care in patients with suspected coronary artery disease: the prospective longitudinal trial of FFR(CT): outcome and resource impacts study. Eur Heart J. Dec 14 2015; 36(47): 3359-67. PMID 26330417
44. Hlatky MA, De Bruyne B, Pontone G, et al. Quality-of-Life and Economic Outcomes of Assessing Fractional Flow Reserve With Computed Tomography Angiography: PLATFORM. J Am Coll Cardiol. Dec 01 2015; 66(21): 2315-2323. PMID 26475205
45. Curzen N, Nicholas Z, Stuart B, et al. Fractional flow reserve derived from computed tomography coronary angiography in the assessment and management of stable chest pain: the FORECAST randomized trial. Eur Heart J. Oct 01 2021; 42(37): 3844-3852. PMID 34269376
46. Yang J, Shan D, Wang X, et al. On-Site Computed Tomography-Derived Fractional Flow Reserve to Guide Management of Patients With Stable Coronary Artery Disease: The TARGET Randomized Trial. Circulation. May 02 2023; 147(18): 1369-1381. PMID 36870065
47. Jensen JM, Bøtker HE, Mathiassen ON, et al. Computed tomography derived fractional flow reserve testing in stable patients with typical angina pectoris: influence on downstream rate of

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invasive coronary angiography. Eur Heart J Cardiovasc Imaging. Apr 01 2018; 19(4): 405-414. PMID 28444153
48. Wang ZQ, Zhou YJ, Zhao YX, et al. Diagnostic accuracy of a deep learning approach to calculate FFR from coronary CT angiography. J Geriatr Cardiol. Jan 2019; 16(1): 42-48. PMID 30800150
49. Nous FMA, Budde RPJ, Lubbers MM, et al. Impact of machine-learning CT-derived fractional flow reserve for the diagnosis and management of coronary artery disease in the randomized CRESCENT trials. Eur Radiol. Jul 2020; 30(7): 3692-3701. PMID 32166492
50. Qiao HY, Tang CX, Schoepf UJ, et al. One-year outcomes of CCTA alone versus machine learning-based FFR CT for coronary artery disease: a single-center, prospective study. Eur Radiol. Aug 2022; 32(8): 5179-5188. PMID 35175380
51. Nørgaard BL, Hjort J, Gaur S, et al. Clinical Use of Coronary CTA-Derived FFR for Decision-Making in Stable CAD. JACC Cardiovasc Imaging. May 2017; 10(5): 541-550. PMID 27085447
52. Lu MT, Ferencik M, Roberts RS, et al. Noninvasive FFR Derived From Coronary CT Angiography: Management and Outcomes in the PROMISE Trial. JACC Cardiovasc Imaging. Nov 2017; 10(11): 1350-1358. PMID 28412436
53. Douglas PS, Hoffmann U, Lee KL, et al. PROspective Multicenter Imaging Study for Evaluation of chest pain: rationale and design of the PROMISE trial. Am Heart J. Jun 2014; 167(6): 796-803.e1. PMID 24890527
54. Qiao HY, Tang CX, Schoepf UJ, et al. Impact of machine learning-based coronary computed tomography angiography fractional flow reserve on treatment decisions and clinical outcomes in patients with suspected coronary artery disease. Eur Radiol. Nov 2020; 30(11): 5841-5851. PMID 32462444
55. Yang L, Xu PP, Schoepf UJ, et al. Serial coronary CT angiography-derived fractional flow reserve and plaque progression can predict long-term outcomes of coronary artery disease. Eur Radiol. Sep 2021; 31(9): 7110-7120. PMID 33630163
56. Liu X, Mo X, Zhang H, et al. A 2-year investigation of the impact of the computed tomography-derived fractional flow reserve calculated using a deep learning algorithm on routine decision-making for coronary artery disease management. Eur Radiol. Sep 2021; 31(9): 7039-7046. PMID 33630159
57. Patel MR, Nørgaard BL, Fairbairn TA, et al. 1-Year Impact on Medical Practice and Clinical Outcomes of FFR CT : The ADVANCE Registry. JACC Cardiovasc Imaging. Jan 2020; 13(1 Pt 1): 97-105. PMID 31005540

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58. Fairbairn TA, Nieman K, Akasaka T, et al. Real-world clinical utility and impact on clinical decision-making of coronary computed tomography angiography-derived fractional flow reserve: lessons from the ADVANCE Registry. Eur Heart J. Nov 01 2018; 39(41): 3701-3711. PMID 30165613
59. Takx RA, Blomberg BA, El Aidi H, et al. Diagnostic accuracy of stress myocardial perfusion imaging compared to invasive coronary angiography with fractional flow reserve meta-analysis. Circ Cardiovasc Imaging. Jan 2015; 8(1). PMID 25596143
60. Curzen NP, Nolan J, Zaman AG, et al. Does the Routine Availability of CT-Derived FFR Influence Management of Patients With Stable Chest Pain Compared to CT Angiography Alone?: The FFR CT RIPCORD Study. JACC Cardiovasc Imaging. Oct 2016; 9(10): 1188-1194. PMID 27568119
61. Baggiano A, Fusini L, Del Torto A, et al. Sequential Strategy Including FFR CT Plus Stress-CTP Impacts on Management of Patients with Stable Chest Pain: The Stress-CTP RIPCORD Study. J Clin Med. Jul 08 2020; 9(7). PMID 32650379
62. Min JK, Berman DS, Budoff MJ, et al. Rationale and design of the DeFACTO (Determination of Fractional Flow Reserve by Anatomic Computed Tomographic AngiOgraphy) study. J Cardiovasc Comput Tomogr. 2011; 5(5): 301-9. PMID 21930103
63. Gulati M, Levy PD, Mukherjee D, et al. 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. Nov 30 2021; 144(22): e368-e454. PMID 34709879
64. National Institute for Health and Care Excellence. HeartFlow FFRCT for estimating fractional flow reserve from coronary CT angiography [MTG32]. 2017; https://www.nice.org.uk/guidance/mtg32. Last updated. Mary 19, 2021.

Policy History

Original Effective Date: 02/15/2017
Current Effective Date: 10/20/2024
10/05/2017 Medical Policy Committee review
10/18/2017 Medical Policy Implementation Committee approval. Policy title changed from "Noninvasive fractional Flow reserve Using Computed Tomography Angiography" to "Coronary Computed Tomography Angiography With Selective

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	Noninvasive Fractional Flow Reserve". Changed coverage from investigational to eligible for coverage for individuals with stable chest pain at intermediate risk of coronary artery disease being considered for invasive coronary angiography. "Positive" added before CCTA to more explicitly state that FRACTIONAL FLOW RESERVE -CT is intended for selective use following CCTA with positive results.
01/01/2018	Coding update
10/04/2018	Medical Policy Committee review
10/17/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2019	Coding update
07/03/2019	Medical Policy Committee review
07/18/2019	Medical Policy Implementation Committee approval. Replaced "patients with stable chest pain at intermediate risk of coronary artery disease (CAD i.e., suspected or presumed stable ischemic heart disease [SIHD])" with "patients who meet coverage criteria for CCTA (as noted in medical policy 00153)" in the eligible for coverage statement.
07/02/2020	Medical Policy Committee review
07/08/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/01/2021	Medical Policy Committee review
07/14/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/07/2022	Medical Policy Committee review
07/13/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/05/2023	Medical Policy Committee review
01/11/2023	Medical Policy Implementation Committee approval. Added a Coverage Criteria section and added a guideline-directed medical therapy (GDMT) for risk factor management and symptom control to the Policy Guidelines section.
05/31/2023	Coding update
07/06/2023	Medical Policy Committee review
07/12/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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Policy # 00537
Original Effective Date: 02/15/2017
Current Effective Date: 10/20/2024

07/02/2024 Medical Policy Committee review
07/10/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 07/2025

Coding

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Coronary Computed Tomography Angiography With Selective Noninvasive Fractional Flow Reserve

Policy # 00537
Original Effective Date: 02/15/2017
Current Effective Date: 10/20/2024

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	75580 Delete code effective 07/01/2023: 0523T Delete code effective 01/01/2024: 0501T, 0502T, 0503T, 0504T
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;

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B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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