BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 6.01.59 Coronary Computed Tomography Angiography With Selective Noninvasive Fractional Flow Reserve

Effective Policy Date: October 1, 2023

Original Policy Date: September 2018

Related Policies:

6.01.20 - Cardiac Applications of Positron Emission Tomography Scanning
6.01.43 - Contrast-Enhanced Computed Tomographic Angiography for Coronary Artery Evaluation

Coronary Computed Tomography Angiography With Selective Noninvasive Fractional Flow Reserve

Description

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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.

OBJECTIVE

The objective of this evidence review is to evaluate whether a noninvasive imaging strategy using coronary computed tomography angiography with a noninvasive assessment of fractional flow reserve improves net health outcome when used to guide decisions about using invasive coronary angiography in patients with stable chest pain and suspected stable ischemic heart disease.

POLICY STATEMENT

The use of noninvasive fractional flow reserve following a positive coronary computed tomography angiography may be considered **medically necessary** to guide decisions about the use of invasive coronary angiography in individuals with stable chest pain at intermediate risk of coronary artery disease (ie, suspected or presumed stable ischemic heart disease).

The use of noninvasive fractional flow reserve not meeting the criteria outlined above is considered **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; 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 visualization of the proximal and mid-segment coronary arteries due to greater cardiac motion and the smaller caliber of coronary vessels in distal locations.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

In November 2014, FFR_{CT} 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 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 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 [FFR_{CT}] 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."

RATIONALE

Summary of Evidence

For individuals with stable chest pain at intermediate risk of coronary artery disease (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; 1 prospective, multi-center, randomized comparative study; 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 from revascularization by demonstrating the absence of functionally significant obstructive coronary artery disease (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.[61,] 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 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."[62,]

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.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
September 2018	New policy	Policy created with literature review through March 6, 2018. Use of FFR-CT is medically necessary 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 FFR-CT is intended for selective use following CCTA with positive results.
September 2019	Replace policy	Policy updated with literature review through March 6, 2019. References added. Policy statements unchanged.
September 2020	Replace policy	Policy updated with literature review through March 9, 2020; reference added. Policy statements unchanged.
September 2021	Replace policy	Policy updated with literature review through March 19, 2021; references added. Policy statements unchanged.
September 2022	Replace policy	Policy updated with literature review through March 31, 2022; references added. Minor editorial change to policy statements; intent unchanged.
September 2023	Replace policy	Policy updated with literature review through April 3, 2023; references added. Policy statements unchanged.