Coronary Computed Tomography Angiography With Selective Noninvasive Fractional Flow Reserve

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.

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 patients 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 (HeartFlow, 2013)(11% to 13% in recent studies; 1,2,3,4, eg, in obese individuals (eg, 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.

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."

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RATIONALITY

Summary of Evidence

For individuals with stable chest pain at intermediate risk of coronary artery disease (CAD) (i.e., suspected or presumed stable ischemic heart disease) being considered for invasive coronary angiography (ICA) who receive noninvasive fractional flow reserve (FFR) measurement following positive coronary computed tomography angiography (CCTA), the evidence includes both direct and indirect evidence: 3 meta-analyses on diagnostic performance; 1 prospective, multi-center nonrandomized comparative study; 2 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, provided by 2 prospective and 5 retrospective studies, 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 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.

National Institute for Health and Care Excellence

In 2017, NICE endorsed fractional flow reserve using coronary computed tomography angiography (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."\(^57\).

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 as part of the NICE pathway 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.

REFERENCES


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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


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