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 (FFR) 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 the net health outcome when a noninvasive imaging strategy using coronary computed tomography angiography with a noninvasive assessment of fractional flow reserve is used to guide decisions about the use of 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

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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; Koo et al, 2011; Min et al, 2012; Nakazato et al, 2013; Nøgaard et al, 2014), eg, in obese individuals (eg, body mass index, \( >35 \text{ kg/m}^2 \)). 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 Food and Drug Administration through the de novo 510(k) process (class II, special controls; Food and Drug Administration product code: PJA). In January 2016, the FFR\(_{CT}\) v2.0 device was cleared through a subsequent 510(k) process.

HeartFlow FFR\(_{CT}\) postprocessing 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 FFRCT [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. FFRCT 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 FFRCT 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."

**RATIONALE**

**Summary of Evidence**

For individuals with stable chest pain at intermediate risk of CAD (ie, suspected or presumed stable ischemic heart disease) being considered for ICA who receive noninvasive FFR measurement following positive CCTA, the evidence includes both direct and indirect evidence: two meta-analyses on diagnostic performance; one prospective, multicenter nonrandomized comparative study; one prospective cohort; two retrospective cohort studies; and a study reporting changes in management associated with CCTA-based strategies with selective addition of FFR-CT and a randomized controlled trial comparing of CCTA alone with ICA. The relevant outcomes are test accuracy and validity, morbid events, QOL, 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 2 retrospective studies, that compares health outcomes observed during 90-day to 1-year follow-up for strategies using CCTA particularly in combination with selective FFR-CT with strategies using ICA or other noninvasive imaging tests. 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. 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 FFR-CT strategy. Moreover, given the available evidence that CCTA alone has been used to select patients to avoid ICA, the studies showing higher specificity of FFR-CT and lower negative likelihood ratio of FFR-CT compared with CCTA alone may be used to build a chain of evidence that CCTA with a selective FFR-CT strategy would

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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 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2017) endorsed fractional flow reserve using coronary computed tomography angiography (FFR-CT), with the following conclusions: “The committee concluded that the evidence suggests that HeartFlow FFRCRT 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 coronary CT angiography (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-CRT 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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