Medical Coverage Policy | Noninvasive Fractional Flow Reserve Using Computed Tomography Angiography

EFFECTIVE DATE: | |
POLICY LAST UPDATED: | |

OVERVIEW
This policy documents the coverage determination for the use of fractional flow reserve using coronary computed tomography angiography preceding invasive coronary angiography in patients with suspected stable ischemic heart disease.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products
The use of fractional flow reserve using coronary computed tomography angiography preceding invasive coronary angiography in patients with suspected stable ischemic heart disease is considered not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure is effective.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for services not medically necessary.

BACKGROUND
Invasively measured fractional flow reserve (FFR) evaluates the severity of ischemia caused by coronary artery obstructions and can predict when revascularization is beneficial. FFR is not a diagnostic test for ischemic heart disease, but evaluates ischemia resulting from a stenosis. It is now possible to obtain FFR noninvasively using computed tomography angiography (CTA)1—so-called FFR-CT (HeartFlow software termed FFRCT; Siemens cFFR) using routinely collected CTA imaging data. 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.

Randomized controlled trials and observational studies have demonstrated that FFR-guided revascularization can improve cardiovascular outcomes, reduce revascularizations, and decrease costs.3 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).4,5 At 1 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.

European guidelines for stable coronary artery disease recommend FFR be used "to identify hemodynamically relevant coronary lesion(s) when evidence of ischaemia 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".7 Guidelines also recommend using "FFR to identify haemodynamically relevant

coronary lesion(s) in stable patients when evidence of ischaemia is not available" (class Ia recommendation).8 U.S. guidelines state that an FFR of 0.80 or less provides level Ia evidence for revascularization for "significant stenoses amenable to revascularization and unacceptable angina despite guideline directed medical therapy."

Measuring FFR during invasive coronary angiography (ICA) requires first 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 are considered to represent significant ischemia while those 0.94 to 1.0 normal. Measurement is valid in the presence of serial stenoses, is unaffected by collateral blood flow, and reproducibility 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.

ICAs are frequently unnecessary in patients with stable ischemic heart disease as evidenced by low diagnostic yields. For example, from a sample of over 132,000 ICAs, Patel et al (2010) found 48.8% of elective ICAs performed in patients with stable angina did not detect obstructive coronary artery disease (left main stenosis ≥50% or ≥70% in a major epicardial or branch >2.0 mm in diameter).12 ICA is clinically useful when patients with stable angina have failed optimal medical therapy and may benefit from revascularization. A test such as FFR-CT that could identify candidates for revascularization—those with significant physiologic obstructions—prior to planned ICA could allow avoiding unnecessary procedures and any adverse consequences.

Only the HeartFlow FFRCT software has been cleared by the U.S. Food and Drug Administration. Imaging analyses require transmitting data to a central location, taking 1 to 3 days to complete. Other prototype software is workstation-based with onsite analyses. FFR-CT cannot be calculated when images lack sufficient quality13 (11% to 13% in recent studies14-17), eg, in obese individuals (eg, body mass index, >35 kg/m2).

REGULATORY STATUS

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

HeartFlow FFRCT 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, 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 [FFRCT] 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."

For individuals who have suspected stable ischemic heart disease and planned invasive coronary angiography (ICA) who receive fractional flow reserve using computed tomography angiography (FFR-CT), the evidence includes studies on test technical performance, 2 meta-analyses of diagnostic accuracy, and 2 studies of patient outcomes. Relevant outcomes are test accuracy and validity, morbid events, quality of life, resource utilization, and treatment-related mortality and morbidity. FFR-CT may offer an effective means to reduce unnecessary ICA with a rationale for a potential role in decision making. Test performance characteristics are consistent with a negative test reducing the probability of significant obstructive disease (eg, vessels with FFR <0.80) and potentially altering a decision to perform ICA. However, outcome data are limited and obtained entirely from nonrandomized studies with comparisons only to usual care. Limitations and uncertainties in

body of evidence examining FFR-CT prevent conclusions concerning the net health outcome. The evidence is insufficient to determine the effects of the technology on health outcomes. Therefore, this service is considered not medically necessary for BlueChiP for Medicare and Commercial products.

CODING

BlueCHiP for Medicare and Commercial Products

There is no specific CPT code for fractional flow reserve using coronary computed tomographic angiography. Claims should be filed with an unlisted CPT code.

RELATED POLICIES

None

PUBLISHED

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