Noninvasive Fractional Flow Reserve Using Computed Tomography Angiography

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)—also called FFR-CT (HeartFlow software termed FFRC; 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. 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). 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 ischemia 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.” Guidelines also recommend using “FFR to identify hemodynamically relevant coronary lesion(s) in stable patients when evidence of ischemia is not available” (class Ia recommendation). U.S guidelines state that an FFR of 0.80 or less provides level Ia evidence for revascularization for significant stenosis 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 stenosis, 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 FFR during a typical ICA is less than 10 minutes.
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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 >2.0mm in diameter). 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, for example those with significant physiologic obstructions, prior to planned ICA could allow avoiding unnecessary procedures and any adverse consequences.

Only the HeartFlow FFR-CT 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 quality (11% to 13% in recent studies), example, in obese individuals (eg, body mass index, >35 kg/m2).

Regulatory Status

In November 2014, FFR-CT simulation software (HeartFlow) was cleared for marketing by the U.S. Food and Drug Administration through the de novo 510(k) process. 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 FFR-CT, 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. FFR-CT 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 FFR-CT 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.”

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.

Policy

The use of fractional flow reserve using computed tomography angiography (FFR-CT) preceding invasive coronary angiography in patients with suspected stable ischemic heart disease is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Noninvasive Fractional Flow Reserve Using Computed Tomography Angiography is covered
Noninvasive Fractional Flow Reserve Using Computed Tomography Angiography

Not applicable

**When Noninvasive Fractional Flow Reserve Using Computed Tomography Angiography is not covered**

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**Policy Guidelines**

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, meta-analyses of diagnostic accuracy, and 2 studies of patient outcomes [one nonrandomized study and one retrospective cohort study (Phase III), with no postadoption use/safety studies (Phase IV) identified]. 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.

**Billing/Coding/Physician Documentation Information**

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: There is no specific CPT code for fractional flow reserve using coronary computed tomographic angiography (FFR-CT).*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

**Scientific Background and Reference Sources**


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Medical Director review 12/2016

Policy Implementation/Update Information

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<th>Date</th>
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<td>1/27/17</td>
<td>New policy developed. Use of noninvasive FFR-CT is considered investigational preceding invasive coronary angiography in patients with suspected stable ischemic heart disease. Medical Director review 12/2016. Policy noticed 1/27/17 for effective date 4/1/17. (jd)</td>
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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.