Medical Policy
Noninvasive Fractional Flow Reserve Using Computed Tomography Angiography

Table of Contents
- Policy: Commercial
- Policy: Medicare
- Authorization Information
- Coding Information
- Description
- Policy History
- Information Pertaining to All Policies
- References

Policy Number: 028
BCBSA Reference Number: 6.01.59
NCD/LCD: N/A

Related Policies
None

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO BlueSM and Medicare PPO BlueSM Members

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 INVESTIGATIONAL.

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th></th>
<th>Outpatient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>This is not a covered service.</td>
</tr>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>This is not a covered service.</td>
</tr>
<tr>
<td>Medicare HMO BlueSM</td>
<td>This is not a covered service.</td>
</tr>
<tr>
<td>Medicare PPO BlueSM</td>
<td>This is not a covered service.</td>
</tr>
</tbody>
</table>

CPT Codes / HCPCS Codes / ICD Codes
Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.
Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

No specific CPT code

Description

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)—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. 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 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”. 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). 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 ≥2.0mm 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—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 quality (11% to 13% in recent studies), eg, in obese individuals (eg, body mass index, >35 kg/m²).

Summary
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, morbidity 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.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
</table>

Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:
- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

References
1. 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 4 2013;61(22):2233-2241. PMID 23562923


