

At a Glance: Medical Necessity Guidelines for FFR_{CT}

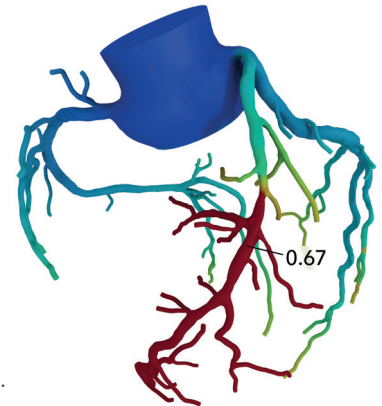
What is the HeartFlow FFR_{CT} Analysis?

The non-invasive HeartFlow FFR_{CT} Analysis is a personalized cardiac test for stable symptomatic patients with suspected coronary artery disease (CAD).

Starting with a standard coronary CT angiogram (CCTA), the HeartFlow FFR_{CT} Analysis creates a color-coded, digital 3D model of the patient's coronary arteries. This aids clinicians in understanding the impact that a patient's coronary blockages have on blood flow to the heart and in determining appropriate treatment.

A CCTA + HeartFlow FFR_{CT} pathway better informs clinicians because it provides the highest diagnostic performance available from a non-invasive test.²

Visit <https://www.heartflow.com/reimbursement-resources/resources-for-payers/> to learn more.



Patients identified to receive FFR_{CT} should meet the following criteria:

- 1. Documented symptoms of suspected CAD; stable symptomatic patients may present in several different ways, including but not limited to the following:**
 - Chest pain, shortness of breath at rest or exertion, dyspnea, elevated heart rate, heart palpitations, anxiety
 - Diaphoresis, or neck, jaw, arm, epigastric or back pain
 - Syncope, near syncope, dizziness, lightheadedness, nausea, vomiting, weakness, or fatigue

- 2. AND positive or indeterminate CCTA with a 30-90% stenosis documented**

Your Medicare Administrative Contractor (MAC) may have separate guidelines regarding stenosis range. Be sure to refer to their policy for additional details.

2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain can be found at <https://www.ahajournals.org/doi/10.1161/CIR.0000000000001029>.

Recommended medical necessity documentation:

- 1. History and Physical (H&P), diagnostic testing, CCTA interpretive report and FFR_{CT} order**
- 2. Clear documentation of presenting cardiac symptoms requiring further investigation through FFR_{CT}**
- 3. Document the need for FFR_{CT} when CCTA is abnormal or indeterminate**
- 4. Documentation of patient BMI**

For Medicare patients in CGS, Palmetto GBA, Noridian, and WPS jurisdictions:

In addition to the previously mentioned Recommended Medical Necessity Documentation, Medicare patients in the CGS, Noridian, Palmetto GBA, and WPS jurisdictions should meet at least one of the following criteria:

- Intermediate-risk* patients with acute or stable chest pain and with no known history of coronary artery stenosis with finding of 40-90% in proximal or middle coronary artery on CCTA¹ **OR**
- Intermediate-risk* patients with acute chest pain and known non-obstructive (<50%) CAD coronary artery stenosis with finding of 40-90% stenosis in proximal or middle coronary artery on CCTA¹ **OR**
- Stable nonobstructive coronary artery disease (<50% stenosis) with persistent symptoms requiring further test, and finding of 40-90% stenosis on CCTA

AND

- Not in conjunction with stress testing* (unless CCTA was not sufficient quality for FFR_{CT} and an alternative study is needed)
- Diagnosis code R93.1 is required to confirm medical necessity and reimbursement of services

FFR_{CT} testing is not reasonable and therefore not covered for patients with the following conditions:

- Prior placement of prosthetic valves
- Prior placement of grafts in coronary bypass surgery
- Suspicion of acute coronary syndrome (where MI or unstable angina have not been ruled out)
- Intracoronary metallic stent
- Status post-heart transplantation
- Recent MI (30 days or less)
- Prior pacemaker or defibrillator lead placement
- Newly diagnosed systolic heart failure, with no prior left heart catheterization
- Left main coronary artery disease with Intermediated Coronary Stenosis (lumen reduction less than or equal to 40%)
- Non-obstructing stenosis (<50% of all major epicardial vessels) on CTA or catheterization in the past twelve months, in the absence of a new symptom complex
- If turnaround times may impact prompt clinical care decisions

Why is the FFR_{CT} order important?

- Confirms the intent of the ordering physician
- Order is based on CCTA results and findings
 - Results must support the need for further functional assessment
- The order must be signed
- Office visit note must be clearly documented
- Documentation should include signs and symptoms of CAD diagnosis
- Orders should link to signs and symptoms consistent with suspected CAD diagnosis codes from CCTA order and include R93.1-Abnormal findings on diagnostic imaging of heart and coronary circulation- code in addition to signs and symptoms
- The FFR_{CT} order along with the CCTA result helps to establish medical necessity and the need for functional analysis

HeartFlow FFR_{CT} performs well even when high calcium is present

- FFR_{CT} provides high diagnostic performance and discrimination of ischemia in patients and vessels over a wide range of coronary calcification scores²

When a CAD-RADS 2.0 score is needed, please refer to the reporting system and publication available in the *Journal of Cardiovascular CT* and at CAD-RADS™ 2.0 - 2022 Coronary Artery Disease-Reporting and Data System.

The most common symptoms and descriptions are chest pain, shortness of breath (SOB), syncope, tightness, and palpitations*

Symptoms should be further described in the detail below:

- Chest pain should indicate
 - Location
 - Radiation
 - Nature
 - Other features (aggravating and relieving factors; duration)
- Shortness of breath
 - Pulmonary edema
 - Acute MI
 - Cardiac arrhythmia
- Palpitations
 - Risk factors
 - Patient description of symptoms
 - Rate and rhythm

What to avoid when ordering FFR_{CT}:

- Use in asymptomatic patients
- Use as a screening test
- Not incorporating, or pulling through the CCTA documented symptoms into the HeartFlow Analysis' clinical documentation

Please contact your local Market Access Field Billing Specialist for additional assistance, or email reimbursement@heartflow.com.

¹ Gulati M, Levy PD, Mukherjee D, et al. 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. 2021:CIR. 0000000000001030.

² Norgaard B, Gaur S, et al. *J Am Coll Cardiol Img.* 2015 Sep, 8 (9) 1045–1055.