Cohere Medicare Advantage Policy - Coronary Computed Tomography Angiography (CCTA), with or without Fractional Flow Reserve (FFR)

Clinical Guidelines for Medical Necessity Review

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Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Other Notices:

Guideline Information:

Specialty Area: Diagnostic Imaging
Guideline Name: Cohere Medicare Advantage Policy - Coronary Computed Tomography Angiography (CCTA), with or without Fractional Flow Reserve (FFR)
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Coronary Computed Tomography Angiogram (CCTA) with or without Fractional Flow Reserve (FFR)

Benefit Category

Not applicable.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.[36-45]

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.

- LCD Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease (L38839)
- LCD Non-Invasive Fractional Flow Reserve (FFR) for Stable Ischemic Heart Disease (L38278)
- LCD Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease (L38613)
- LCD Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease (L38615)
- LCD Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease (L39075)
- LCD Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease (L38771)
- LCD Cardiac Computed Tomography & Angiography (CCTA) (L33423)
- LCD Cardiac Computed Tomography (CCT) and Coronary Computed Tomography Angiography (CCTA) (L33947)
- LCD Coronary Computed Tomography Angiography (CCTA) (L35121)
- LCD Cardiac Computed Tomography (CCT) and Coronary Computed Tomography Angiography (CCTA) (L33559)
- Billing and Coding: Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease (A58473)
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- Billing and Coding: Non-Invasive Fractional Flow Reserve (FFR) for Stable Ischemic Heart Disease (A58406)
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- Billing and Coding: Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease (A58095)
- Billing and Coding: Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease (A58814)
- Billing and Coding: Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease (A58359)
- Billing and Coding: Cardiac Computed Tomography & Angiography (CCTA) (A56691)
- Billing and Coding: Cardiac Computed Tomography (CCT) and Coronary Computed Tomography Angiography (CCTA) (A56737)
- Billing and Coding: Cardiac Computed Tomography (CCT) and Coronary Computed Tomography Angiography (CCTA) (A56451)
- Billing and Coding: Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-QCT)/Coronary Plaque Analysis (AI-CPA) (DA59813)
- Billing and Coding: Coronary Computed Tomography Angiography (CCTA)(A57552)

Recommended Clinical Approach

Computed tomography coronary angiography (CCTA) is a non-invasive alternative to cardiac catheterization performed with iodinated contrast. The radiologist may consider additional phases, dynamic sequences, positioning of the patient, and the use of markers. The referring clinician is responsible for the appropriate clinical indication in consultation with a cardiac imaging expert. The patient's pertinent medical history should justify the exam. The physician laboratory director should choose the scanning protocol for the study before the patient's arrival. Following a positive CCTA, non-invasive fractional flow reserve (FFR) may be medically necessary to guide decisions about invasive coronary angiography in patients with intermediate or high-risk coronary anatomy on imaging.[1-5] CT-FFR is not recommended in patients with complex congenital heart disease.

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of computed tomography coronary angiography (CCTA). This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary

procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.[24,29-31]
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.[32] Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.[32]
- Increased healthcare costs and complications from the inappropriate use of additional interventions.[26]

The clinical benefits of using these criteria include:

- Accuracy: CCTA has exceptional diagnostic accuracy, with a high degree of sensitivity (91%) and specificity (92%) for the detection of coronary artery disease.[1] Further, CCTA in conjunction with FFR holds increased sensitivity and specificity of diagnostic accuracy than standard CCTA alone.[9,21]
- Noninvasive: As a cardiac imaging modality, CCTA is relatively noninvasive when compared to other modalities, such as invasive cardiac angiography (ICA).[1] It is widely accepted that noninvasive procedures are less costly, associated with fewer complications, and preferred by both patients and providers.[27,28]
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous

clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- ➔ **Computed tomography coronary angiography (CCTA) with or without fractional flow reserve (FFR)** is considered appropriate if **ANY** of the following is **TRUE**[3,6-12]:
  - ◆ There is a suspicion of cardiac anomaly[12] including **ANY** of the following[36,37];
    - Evaluation of cardiac mass (suspected tumor or thrombus)
    - Evaluation of pericardial conditions (mass, constrictive pericarditis or complications of cardiac surgery)
    - Complex congenital heart disease (e.g., anomalies of coronary or pulmonary circulation, great vessels and cardiac chamber and valves); OR
  - ◆ Possible acute coronary syndrome where standard diagnostic testing including EKG and cardiac enzymes are nondiagnostic or indeterminate for myocardial injury[36-39]; **OR**
  - ◆ No known coronary artery disease (CAD) with an intermediate or high pre-test probability of obstructive CAD (based on the CAD Consortium Calculator)[33] and **ANY** of the following[3,12]:
    - Chest pain (or ischemic equivalent, including dyspnea) after an inconclusive or abnormal exercise ECG or stress imaging study; **OR**
    - Chest pain (or ischemic equivalent, including dyspnea) after a negative stress test but with high clinical suspicion of CAD; **OR**
    - Chest pain (or ischemic equivalent, including dyspnea); **OR**
  - ◆ CAD is known and previously determined to be non-obstructive (less than 70%), but there has been a clinical change that suggests CAD in the native coronary arteries has progressed[13]; **OR**

- Previous coronary revascularization with bypass or percutaneous intervention was performed and there is a clinical change in cardiac status[38]; **OR**
- New or unexplained cardiomyopathy with an ejection fraction less than 40%[5,36]; **OR**
- Fractional Flow Reserve (FFR) is for **ANY** of the following[20,21,40-45]:
  - For functional evaluation of coronary CTA lesions, which are 40-90% stenosed in a proximal to a middle coronary segment on CCTA[3,20]; **OR**
  - For evaluating multivessel disease and identifying culprit lesions seen on CCTA that may be causing symptoms; **OR**
  - For evaluating the physiologic severity of multiple lesions in a single vessel[3]; **OR**
- Preoperative evaluation when **ANY** of the following is **TRUE**:
  - Valve or other cardiac surgery
  - High risk vascular surgery (e.g., aneurysm repair)
  - Renal transplant or other solid organ transplant**; OR**
- Annual surveillance post-cardiac transplant[34,35]; **OR**
- Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:
  - New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
  - One-time clarifying follow-up of a prior indeterminate finding; **OR**
  - In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

➔ **Computed tomography coronary angiography (CCTA)** is not considered appropriate if **ANY** of the following is **TRUE**[5,11]:

- If **ANY** of the following is **TRUE** if contrast is used:
  - History of anaphylactic allergic reaction to iodinated contrast media; **OR**
  - Renal insufficiency with no provided detailed guidelines; **OR**

- Normal coronary angiogram or CCTA with no stenosis or plaque within the last two years and stable symptoms; **OR**
- Normal stress test within the previous year (given adequate stress) with stable symptoms; **OR**
- If FFR is performed, it is not considered appropriate if **ANY** of the following conditions is **TRUE**[3,21]:
    - The original CCTA was of suboptimal quality; **OR**
    - The patient is not a candidate for revascularization; **OR**
    - Coronary anatomy seen on CCTA is non-obstructive[20].

*NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.
**NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.[24,25]

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.[24,25]

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring

multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.[24,25]

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.[24,25]

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
75574	Computed tomographic angiography (CTA), heart, coronary arteries and bypass grafts (when present); with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation)
75580	Noninvasive estimate of coronary fractional flow reserve (FFR) derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified healthcare professional

Medical Evidence

In the 2021 chest pain guideline for the American College of Cardiology, Gulati et al. give several recommendations for the use of coronary computed tomography angiography (CCTA), including for intermediate-risk patients with acute chest pain and no known coronary artery disease (CAD) who require diagnostic testing following a negative evaluation for acute coronary syndrome. Additionally, CCTA is a proven approach for evaluating patients with stable chest pain with a strong (Class 1) strength of recommendation[3]. The writers state that CCTA helps exclude atherosclerotic plaque and obstructive CAD. A recommendation was given for CCTA to diagnose obstructive CAD in patients at intermediate risk with acute pain and mildly abnormal previous stress testing. When evaluating patients in the emergency department with acute chest pain, CCTA may reduce the time to diagnosis and possible earlier safe discharge.[3]

Taylor et al. (2010) developed appropriate use criteria for cardiac computed tomography. The use of CCTA in low or intermediate-risk patients with pretest probability for CAD may be considered. Testing in high-risk patients, routinely repeating testing, and use for general cardiac screening were not viewed favorably. Lowest appropriateness ratings were assigned in urgent presentations with acute symptoms with suspicion of acute coronary syndrome, such as in definite myocardial infarction (MI), persistent ST-segment elevation on ECG (when MI excluded), and acute chest pain of uncertain cause prompting rule out of pulmonary embolism, aortic dissection and acute coronary syndrome.[6]

Driessen and colleagues (2019) published post hoc single-center study results comparing CCTA, FFR, and perfusion imaging for ischemia diagnosis for the American College of Cardiology. The 208 patients were enrolled with suspicion of CAD and underwent CCTA, SPECT, and PET scans with routine FFR study of all major coronary arteries. All patients were prospectively tested noninvasively and invasively with FFR within 2 weeks, regardless of their results. Of the 208 patients, the CCTA images of 75% of patients were entirely sufficient for evaluation by FFR_{CT}. The group concluded that FFR_{CT} showed high diagnostic performance for vessel-specific ischemia, provided that the CCTA

images were adequate for FFR evaluation. PET scanning yielded the highest diagnostic performance due to the often high rejection rate of the FFR_{CT}.[9]

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Ischemic Heart Disease. Published April 17, 2025. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38771&ver=17&bc=0

Clinical Guideline Revision History/Information

Original Date: September 12, 2024		
Review History		
Version 1.1	March 27, 2025	Updated policy per CMS revisions for 11/24/24 Updated Revision Date Updated Links and Bookmarks
Version 1.2	April 22, 2025	Updated policy per CMS revisions for 03/13/2025 Updated Revision Date Updated Links and References
Version 1.3	May 15, 2025	Updated policy per CMS revisions for 04/17/2025 Updated Revision Date Updated Links and References