



## FEP Medical Policy Manual

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### FEP 6.01.03 Computed Tomography to Detect Coronary Artery Calcification

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**Annual Effective Policy Date: January 1, 2024**

**Original Policy Date: December 2011**

**Related Policies:**

6.01.43 - Contrast-Enhanced Computed Tomographic Angiography for Coronary Artery Evaluation

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## Computed Tomography to Detect Coronary Artery Calcification

### Description

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Several types of fast computed tomography (CT) imaging, including electron-beam CT and spiral CT, allow the quantification of calcium in coronary arteries. Coronary artery calcium (CAC) is associated with coronary artery disease (CAD). The use of CAC scores has been studied in the prediction of future risk of CAD and in the diagnosis of CAD in symptomatic patients.

## Detection

Electron-beam computed tomography (EBCT; also known as ultrafast CT) and spiral CT (or helical CT) may be used as an alternative to conventional CT scanning due to faster throughput. In both methods, the speed of image acquisition gives them unique value for imaging a moving heart. The rapid image acquisition time virtually eliminates motion artifact related to cardiac contraction, permitting visualization of the calcium in the epicardial coronary arteries. Electron-beam computed tomography software permits quantification of calcium area and density, which are translated into calcium scores. Calcium scores have been investigated as a technique for detecting CAC, both as a diagnostic technique in symptomatic patients to rule out an atherosclerotic etiology of symptoms or, in asymptomatic patients, as an adjunctive method for risk stratification for CAD.

Electron-beam computed tomography and multidetector CT were initially the primary fast CT methods for measurement of CAC. A fast CT study for CAC measurement takes 10 to 15 minutes and requires only a few seconds of scanning time. More recently, computed tomography angiography has been used to assess coronary calcium. Because of the basic similarity between EBCT and computed tomography angiography in measuring coronary calcium, it is expected that computed tomography angiography provides information on coronary calcium that is similar to EBCT.

Computed tomography scan-derived coronary calcium measures have been used to evaluate coronary atherosclerosis. Coronary calcium is present in coronary atherosclerosis, but atherosclerosis detected may or may not be causing ischemia or symptoms. Coronary calcium measures may be correlated with the presence of critical coronary stenoses or serve as a measure of the patient's proclivity toward atherosclerosis and future coronary disease. Thus, coronary calcium could serve as a variable to be used in a risk assessment calculation to determine appropriate preventive treatment in asymptomatic patients. Alternatively, in other clinical scenarios, coronary calcium scores might help determine whether there is an atherosclerotic etiology or component to the presenting clinical problem in symptomatic patients, thus helping to direct further workup for the clinical problem. In this second scenario, a calcium score of 0 usually indicates that the patient's clinical problem is unlikely to be due to atherosclerosis and that other etiologies should be more strongly considered. In neither case does the test determine a specific diagnosis. Most clinical studies have examined coronary calcium for its potential use in estimating the risk of future coronary heart disease events.

## Nomenclature

Coronary calcium levels can be expressed in many ways. The most common method is the Agatston score, which is a weighted summed total of calcified coronary artery area observed on CT. This value can be expressed as an absolute number, commonly ranging from 0 (low-risk) to 400 (high-risk). These values can be translated into age- and sex-specific percentile values. Different imaging methods and protocols will produce different values based on the specific algorithm used to create the score, but the correlation between any 2 methods appears to be high, and scores from 1 method can be translated into scores from a different method.

## OBJECTIVE

The objective of this evidence review is to evaluate the net health outcome of the use of computed tomography to detect coronary artery calcium in 2 settings:

1. For patients with risk of coronary artery disease, who are asymptomatic, does the use of coronary artery calcium scoring as an adjunct standard risk stratification to manage treatment result in improvement in cardiac risk factors?
2. For patients with chest pain symptoms suggestive of coronary artery disease, compared to standard diagnostic testing, does the use of coronary artery calcium scoring to rule out coronary artery disease reduce the use of unnecessary invasive coronary angiography?

## POLICY STATEMENT

The use of computed tomography to detect coronary artery calcification is considered **not medically necessary**.

## POLICY GUIDELINES

When quantitative assessment is performed as part of the same encounter as contrast-enhanced cardiac computed tomography or coronary computed tomography angiography, it is included in the service.

The primary fast computed tomography methods for this determination are electron beam computed tomography and multidetector computed tomography.

## BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

Coverage eligibility of computed tomography scanning to detect coronary artery calcium may be limited by contractual exclusions for screening tests.

## FDA REGULATORY STATUS

Many models of CT devices, including EBCT and other ultrafast CT devices, have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. U.S. FDA product code: JAK.

## RATIONALE

### Summary of Evidence

For individuals who are asymptomatic with the risk of coronary artery disease (CAD) who receive coronary artery calcium (CAC) scoring, the evidence includes multiple systematic reviews, randomized controlled trials (RCTs), and nonrandomized observational studies. Relevant outcomes are overall survival (OS), test accuracy and validity, morbid events, and resource utilization. There is extensive evidence on the predictive value of CAC score screening for cardiovascular disease (CVD) among asymptomatic patients, and this evidence has demonstrated that scanning has incremental predictive accuracy above traditional risk factor measurement. However, high-quality evidence demonstrating that the use of CAC scores in clinical practice leads to changes in patient management or in individual risk behaviors that improve cardiac outcomes is limited. One meta-analysis of RCTs reported no significant change in coronary risk profile, downstream testing, or revascularization following screening using CAC scoring compared with no CAC scoring. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with signs and/or symptoms suggestive of CAD who receive CAC scoring before other diagnostic testing, the evidence includes systematic reviews, RCTs, and nonrandomized observational studies. Relevant outcomes are OS, test accuracy and validity, morbid events, and resource utilization. Coronary artery calcium scoring has potential as a diagnostic test to rule out CAD in patients presenting with symptoms or as a "gatekeeper" test before invasive imaging is performed. Evidence from observational studies has suggested that negative results on CAC scoring rule out CAD with good reliability. However, the evidence has been inconsistent, with some studies reporting a lack of value when using a 0 calcium score to rule out CAD. Further prospective trials would be needed to demonstrate that such a strategy is effective in practice and is at least as effective as alternative strategies for ruling out CAD. To demonstrate that use of calcium scores improves the efficiency or accuracy of the diagnostic workup of symptomatic patients, rigorous studies defining exactly how CAC scores would be used in combination with other tests to triage patients would be necessary. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## SUPPLEMENTAL INFORMATION

### Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

#### Practice Guideline - American Heart Association/American College of Cardiology

The American College of Cardiology and American Heart Association (2018) Clinical Practice Guidelines on the Management of Blood Cholesterol state, "When risk status is uncertain, a coronary artery calcium (CAC) score is an option to facilitate decision making in adults 40 to 75 years of age."<sup>41</sup> The guidelines further note, "One purpose of CAC scoring is to reclassify risk identification of patients who will potentially benefit from statin therapy. This is especially useful when the clinician and patient are uncertain whether to start a statin. Indeed, the most important recent observation has been the finding that a CAC score of 0 indicates a low ASCVD risk for the subsequent 10 years. Thus, measurement of CAC potentially allows a clinician to withhold statin therapy in patients showing 0 CAC."

With regard to the prognostic significance of CAC, the guideline "makes use of the available data to predict the risk associated with CAC."<sup>41</sup> The guideline notes that "these data need to be amplified by new and ongoing studies to guide treatment decisions" and that "particular uncertainty exists about the predictive value of intermediate CAC scores." Additionally, there are concerns regarding the predictive significance of a CAC score of 0, which must be further verified in follow-up studies. For patients with a 0 score, "it is currently uncertain when and if follow-up CAC measurements should be done to reassess risk status."

The American College of Cardiology and American Heart Association (2019) Guideline on the Primary Prevention of Cardiovascular Disease is in line with the blood cholesterol guideline stating that adults (40 to 75 years of age) who are being evaluated for cardiovascular disease prevention should initially undergo 10-year atherosclerotic cardiovascular disease (ASCVD) risk estimation with a clinician-patient risk discussion before starting pharmacological therapy.<sup>42</sup> The guideline also notes that assessing for other risk-enhancing factors can help guide decision making "about preventive interventions in select individuals, as can CAC scanning." The guideline specifically states the following recommendation regarding assessment of cardiovascular risk and CAC:

- In adults at intermediate risk ( $\geq 7.5\%$  to  $< 20\%$  10-year ASCVD risk) or selected adults at borderline risk ( $5\%$  to  $< 7.5\%$  10-year ASCVD risk), if risk-based decisions for preventive interventions remain uncertain, it is reasonable to measure a CAC score to guide clinician-patient risk discussion [Class (Strength) of Recommendation: IIa; Level (Quality) of Evidence: B-NR]. A IIa class of recommendation is of moderate strength based on moderate quality nonrandomized studies.

The American Heart Association, American College of Cardiology (2021) Guideline on Evaluation and Diagnosis of Chest Pain includes a recommendation for CAC as first-line testing in patients with stable chest pain with no known coronary artery disease and low likelihood of obstruction.<sup>43</sup> The guidelines recommend the addition of CAC may also be useful for intermediate-high risk patients with stable chest pain and no known coronary artery disease undergoing stress testing.

## Special Report - American Heart Association/American College of Cardiology

The American Heart Association and the American College of Cardiology (2019) issued a special report on the use of risk assessment tools to guide decision-making in the primary prevention of ASCVD.<sup>44</sup> This report includes an algorithm of clinical approaches to incorporate CAC measurement in risk assessment for borderline- and intermediate-risk patients:

"For borderline-risk (10-year risk  $5\%$  to  $< 7.5\%$ ) and intermediate-risk ( $7.5\%$  to  $< 20\%$ ) patients who are undecided regarding statin therapy, or when there is clinical uncertainty regarding the net benefit, consider the value of additional testing with measurement of CAC. If CAC is measured, interpret results as follows:

- a. CAC score of 0 indicates that a borderline- or intermediate-risk individual is reclassified to a 10-y event rate lower than predicted, and below the threshold for benefit from a statin. Consider avoiding or postponing statin therapy unless there is a strong family history of premature ASCVD, history of diabetes mellitus, or heavy cigarette smoking. Consider repeat CAC measurement in 5 years if patient remains at borderline or intermediate risk.
- b. CAC score 1 to 99 and  $< 75$ th percentile for age/sex/race/ethnicity indicates that there is subclinical atherosclerosis present. This may be sufficient information to consider initiating statin therapy, especially in younger individuals, but does not indicate substantial reclassification of the 10-y risk estimate. Consider patient preferences and, if statin decision is postponed, consider repeat CAC scoring in 5 years.
- c. CAC score 100 or  $> 75$ th percentile for age/sex/race/ethnicity indicates that the individual is reclassified to a higher event rate than predicted, that is above the threshold for statin benefit. Statin therapy is more likely to provide benefit for such patients."

## National Institute for Health and Care Excellence

For patients with "stable chest pain who cannot be excluded by clinical assessment alone," the National Institute for Health and Care Excellence recommended CT using 64-slice imaging.<sup>45</sup>

## U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force (2018) updated its recommendations on the use of nontraditional or novel risk factors in assessing coronary heart disease risk in asymptomatic adults with no known cardiovascular disease.<sup>46,47</sup> Calcium score was 1 of 3 nontraditional risk factors considered. Reviewers concluded the current evidence was insufficient to assess the balance of benefits and harms of adding any of the nontraditional risk factors studied to traditional risk assessment in asymptomatic adults with no known cardiovascular disease.

## Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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## POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

| Date           | Action         | Description  |
|----------------|----------------|--|
| December 2011  | New policy     |  |
| June 2012      | Replace policy | Policy statement changed to not medically necessary.   |
| September 2013 | Replace policy | Policy updated with literature search; references added and deleted. No change in policy statement.  |
| September 2014 | Replace policy | Policy updated with literature review, adding references 7, 11, 21, 22,24-26, 29, 31 and 32. Editorial changes were made to the rationale and summary. No changes were made to the policy statement.   |
| September 2015 | Replace policy | Policy updated with literature review; references 12, 16, 24, 26, 29, 31,and 38 added. Policy statement unchanged.   |
| December 2016  | Replace policy | Policy updated with literature review; references 2, 15, and 37 added. Policy statement unchanged.   |
| December 2017  | Replace policy | Policy updated with literature review through July 26, 2017; references 2-7, 11, 14, 16, 18, 24-25, 31-33, and 40 added. Policy statement unchanged but "not medically necessary, corrected to "investigational,.  |
| December 2018  | Replace policy | Policy updated with literature review through August 9, 2018; references3-5 and 40-42 added. Policy statement unchanged.   |
| December 2019  | Replace policy | Policy updated with literature review through July 29, 2019; references added. Added Supplemental Information section updated. Clarification added to policy objective "review does not address computed tomography coronary artery calcium scoring for asymptomatic patients. " Policy statement unchanged. |
| December 2020  | Replace policy | Policy updated with literature review through August 4, 2020; references added. Policy statements unchanged.   |
| December 2021  | Replace policy | Policy updated with literature review through July 28, 2021; reference added. Use in asymptomatic patients added to policy objective. Policy statement unchanged.  |
| December 2022  | Replace policy | Policy updated with literature review through July 18, 2022; references added. Policy statements unchanged.  |
| December 2023  | Replace policy | Policy updated with literature review through July 27, 2023; no references added. Policy statements unchanged, but 'investigational' changed to 'not medically necessary' due to 510K process.   |

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.