Computed Tomography to Detect Coronary Artery Calcification

Description

Several types of fast computed tomography imaging, including electron-beam computed tomography and spiral computed tomography, 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 diagnosis of CAD in symptomatic patients.

OBJECTIVE

The objective of this evidence review is to evaluate whether the use of computed tomography coronary artery calcium scoring reduces the risk of coronary artery disease among symptomatic patients. This review does not address computed tomography coronary artery calcium scoring for asymptomatic patients due to coverage eligibility.

POLICY STATEMENT

The use of computed tomography to detect coronary artery calcification is considered investigational.

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POLICY GUIDELINES

None

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 non-preventative benefit screening tests. (See USPSTF determination below).

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 through the 510(k) process. Food and Drug Administration product code: JAK.

RATIONALE

Summary of Evidence

For individuals with signs and/or symptoms suggestive of coronary artery disease (CAD) who receive coronary artery calcium (CAC) scoring before other diagnostic testing, the evidence includes prospective and retrospective nonrandomized studies. The relevant outcomes are overall survival (OS), test accuracy and validity, morbid events, and resource utilization. CAC 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 zero 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 the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

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 atherosclerotic CVD. The guidelines include 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.

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b. CAC score 1 to 99 and <75th 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 >75th 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."

The American College of Cardiology and the American Heart Association (2018) Clinical Practice Guidelines on the Management of Blood Cholesterol state, "When risk status is uncertain, a CAC score is an option to facilitate decision-making in adults ≥40 years of age." 36 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 zero 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 zero CAC."

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.37

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 persons. 38-39 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 for cardiovascular disease in asymptomatic persons.

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.

REFERENCES

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Diagnosis and screening for coronary artery disease with electron beam computed tomography. TEC Assessments. 1998;Volume 13:Tab 27.


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

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>December 2011</td>
<td>New policy</td>
<td>Policy statement changed to not medically necessary.</td>
</tr>
<tr>
<td>June 2012</td>
<td>Replace policy</td>
<td>Policy updated with literature search; references added and deleted. No change in policy statement.</td>
</tr>
<tr>
<td>September 2013</td>
<td>Replace policy</td>
<td>Policy updated with literature review; references 7, 11, 21, 22, 24-26, 29, 31 and 32. Editorial changes were made to the rationale and summary.</td>
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<tr>
<td>September 2014</td>
<td>Replace policy</td>
<td>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.</td>
</tr>
<tr>
<td>September 2015</td>
<td>Replace policy</td>
<td>Policy updated with literature review; references 12, 16, 24, 26, 29, 31, and 38 added. Policy statement unchanged.</td>
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<tr>
<td>December 2016</td>
<td>Replace policy</td>
<td>Policy updated with literature review; references 2, 15, and 37 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>December 2017</td>
<td>Replace policy</td>
<td>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 &quot;not medically necessary&quot; corrected to &quot;investigational&quot;.</td>
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<tr>
<td>December 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through August 9, 2018; references 3-5 and 40-42 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>December 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through July 29, 2019; references added. Added Supplemental Information section updated. Clarification added to policy objective &quot;review does not address computed tomography coronary artery calcium scoring for asymptomatic patients due to coverage eligibility.&quot; Policy statement unchanged.</td>
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