FEP 6.01.03 Computed Tomography to Detect Coronary Artery Calcification

Effective Date: January 15, 2018

Related Policies:
6.01.43 Contrast-Enhanced Computed Tomography Angiography for Coronary Artery Evaluation

Computed Tomography to Detect Coronary Artery Calcification

Description
Several types of fast computed tomography (CT) imaging, including electron-beam computed tomography 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.

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.

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

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

RATIONALE
Summary of Evidence
For individuals who are asymptomatic with risk of CAD who receive CAC scoring, the evidence includes multiple systematic reviews, randomized controlled trials, and nonrandomized observational studies. Relevant outcomes are overall survival, test accuracy and validity, morbidity events, and resource utilization. There is extensive evidence on the predictive value of CAC score screening for cardiovascular disease 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 lacking. A meta-analysis of randomized controlled trials 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 the effects of the technology on health outcomes.

For individuals with signs and/or symptoms suggestive of CAD who receive CAC scoring before other diagnostic testing, the evidence includes prospective and retrospective nonrandomized studies. Relevant
outcomes are overall survival, 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 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
In 2006, the American Heart Association (AHA) issued a scientific statement on the use of cardiac computed tomography (CT).35 Most of the document reviewed the utility of calcium scoring for the use of determining prognosis and diagnosis. In addition to reviewing a large body of evidence on calcium scoring, clinical recommendations were offered. No indications received a class I recommendation (ie, evidence and/or agreement that the procedure is useful and effective) (see Table 1).

Table 1 Use of CAC Scoring to Assess Cardiovascular Risk

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
</tr>
</thead>
<tbody>
<tr>
<td>“…patients with chest pain with equivocal or normal ECGs and negative cardiac enzymes…”</td>
<td>IIb</td>
</tr>
<tr>
<td>“…determining the etiology of cardiomyopathy…”</td>
<td>IIb</td>
</tr>
<tr>
<td>“…symptomatic patients, … in the setting of equivocal treadmill or functional tests”</td>
<td>IIb</td>
</tr>
<tr>
<td>Asymptomatic patients with “intermediate-CAD risk patients (eg, those with a 10% to 20% Framingham 10-year risk estimate)…”</td>
<td>IIb</td>
</tr>
<tr>
<td>“Asymptomatic persons … found to be at low risk (&lt;10% 10-year risk) and high risk (&gt;20% 10-year risk) do not benefit…..”</td>
<td>III</td>
</tr>
<tr>
<td>“…It is not recommended … in asymptomatic persons to establish the presence of obstructive disease for revascularization…..”</td>
<td>III</td>
</tr>
<tr>
<td>“Serial imaging for assessment of progression of coronary calcification is not indicated…..”</td>
<td>III</td>
</tr>
<tr>
<td>“…hybrid nuclear/CT imaging is not recommended…..”</td>
<td>III</td>
</tr>
</tbody>
</table>

Class IIb evidence indicates usefulness or efficacy has been less well-established; class III evidence indicates the procedure or treatment is not useful or possibly harmful.

CAD: coronary artery disease; COR: class of recommendation; CT: computed tomography; ECG: electrocardiograph.

American College of Cardiology Foundation et al
A joint 2007 clinical consensus document by the American College of Cardiology Foundation (ACCF), AHA, and other medical societies36 reviewed much of the same evidence as the 2006 AHA scientific statement. Formal grading of evidence and classification of clinical recommendations were not reported. This document concluded that the indications receiving an IIb recommendation in the 2006 scientific statement “may be reasonable.”
In 2010, ACCF, AHA, and 7 others societies released recommendations on calcium scoring as part of their joint guidelines on the management of cardiovascular risk in asymptomatic patients. Recommendations included in Table 2.

Table 2 Use of Calcium Scoring to Diagnose and Manage Stable Ischemic Heart Disease

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measurement of CAC is reasonable for cardiovascular risk assessment in asymptomatic adults at intermediate risk (10% to 20% 10-year risk).</td>
<td>Ila</td>
<td>B</td>
</tr>
<tr>
<td>Measurement of CAC may be reasonable for cardiovascular risk assessment in persons at low to intermediate risk (6% to 10% 10-year risk).</td>
<td>Iib</td>
<td>B</td>
</tr>
<tr>
<td>No Benefit. Persons at low risk (&lt;6% 10-year risk) should not undergo CAC measurement for cardiovascular risk assessment.</td>
<td>III</td>
<td>B</td>
</tr>
</tbody>
</table>

CAC: coronary artery calcium; COR: class of recommendation; LOE: level of recommendation.

In 2012, ACCF, AHA, and 5 other societies released guidelines on the diagnosis and management of patients with stable ischemic heart disease (IHD) that include recommendations on CAC scoring:

Class IIb recommendation: For patients with a low to intermediate pretest probability of obstructive IHD, noncontrast cardiac computed tomography to determine the coronary artery calcium score may be considered. (Level of Evidence: C)

In 2014, ACCF, AHA, and 4 other medical associations updated their 2012 guidelines on the diagnosis and management of patients with stable IHD and made no additional recommendations for CAC scoring.

**National Institute for Health and Care Excellence**

For patients with stable chest pain with a 10% to 29% likelihood of 10 coronary artery disease (CAD), the National Institute for Health and Care Excellence has recommended CT using at least 64-slice imaging. The guidance also stated:

"...to minimize exposure... a calcium score should be undertaken initially, with no further testing if this is zero on the grounds that significant CAD has been ruled out with a high degree of accuracy; sensitivity is up to 99%.”

In this population, for calcium scores from 1 to 400 Agatston units, the Institute has recommended proceeding to coronary computed tomography angiography. For calcium score greater than 400 Agatston units, proceeding straight to invasive coronary angiography has been proposed.

**U.S. Preventive Services Task Force Recommendations**

The U.S. Preventive Services Task Force (USPSTF) issued recommendations on the use of nontraditional or novel risk factors in assessing coronary heart disease risk in asymptomatic persons in 2009. Calcium score was 1 of 9 risk factors considered in the report. The authors concluded that the current evidence was insufficient to assess the balance of benefits and harms of using any of the nontraditional risk factors studied to assess the risk of coronary disease in asymptomatic persons. In USPSTF’s focused review of 5 studies, which it judged to have valid study designs, USPSTF found wide variation in the estimates of the risk ratio for higher calcium scores. Higher quality studies had lower relative risks for a given difference in calcium score.

**Medicare National Coverage**

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.
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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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37. Taylor AJ, Corque M, Hodgson JM, et al. ACCF/SCCT/ACR/AHA/ASE/ASNC/NASC|SCAI/SCMR 2010 appropriate use criteria for cardiac computed tomography. A report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, the Society of Cardiovascular Computed Tomography, the American College of Radiology, the American Heart Association, the American Society of Echocardiography, the American Society of Nuclear Cardiology, the North American Society for Cardiovascular Imaging, the Society for...
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### POLICY HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<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>Update 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>Update 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>Update Policy</td>
<td>Policy updated with literature review; references 12, 16, 24, 26, 29, 31, and 38 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>December 2016</td>
<td>Update 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>Update 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 “not medically necessary” corrected to “investigational”.</td>
</tr>
</tbody>
</table>

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