Contrast-Enhanced Computed Tomographic Angiography for Coronary Artery Evaluation

Description

Contrast-enhanced coronary computed tomography angiography (CCTA) is a noninvasive imaging test that requires the use of intravenously administered contrast material and high-resolution, high-speed computed tomography machinery to obtain detailed volumetric images of blood vessels. It is a potential diagnostic alternative to current tests for cardiac ischemia (ie, noninvasive stress testing and/or coronary angiography).

OBJECTIVE

The objective of this evidence review is to evaluate whether coronary computed tomography angiography improves health outcomes compared with alternative testing strategies. Three major indications for cardiac or coronary computed tomography angiography are considered: (1) evaluation of patients with acute chest pain without known coronary disease presenting in the emergency department setting, (2) evaluation of stable patients with signs and symptoms of coronary artery disease in the non-emergency department setting, and (3) evaluation of anomalous coronary arteries.
POLICY STATEMENT

Contrast-enhanced coronary computed tomography angiography for evaluation of patients without known coronary artery disease and acute chest pain in the emergency department setting is considered medically necessary.

Contrast-enhanced coronary computed tomography angiography for evaluation of patients with stable chest pain and meeting guideline criteria for a noninvasive test in the outpatient setting (see Policy Guidelines) is considered medically necessary.

Contrast-enhanced coronary computed tomography angiography for evaluation of anomalous (native) coronary arteries in patients in whom they are suspected may be considered medically necessary.

Contrast-enhanced coronary computed tomography angiography for coronary artery evaluation is considered investigational for all other indications.

POLICY GUIDELINES

The 2012 collaborative medical association guidelines for the diagnosis and management of patients with stable heart disease (Fihn et al, 2012) list several class I recommendations on use of noninvasive testing in patients with suspected stable ischemic heart disease. A class I recommendation indicates that a test should be performed. In general, patients with at least intermediate risk (10%-90% risk by standard risk prediction instruments) are recommended to have some type of test, the choice depending on interpretability of the electrocardiogram, capacity to exercise, and presence of comorbidity.

BENEFIT APPLICATION

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

FDA REGULATORY STATUS

CCTA is performed using multidetector-row computed tomography, and multiple devices have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process. Current machines are equipped with at least 64 detector rows. Intravenous iodinated contrast agents used for CCTA also have received Food and Drug Administration approval.

RATIONALE

Summary of Evidence

For individuals who have acute chest pain and suspected coronary artery disease (CAD) in the emergency setting, at intermediate- to low-risk, who receive contrast-enhanced coronary computed tomography angiography (CCTA), the evidence includes several randomized controlled trials (RCTs), a systematic review, and a prospective head-to-head study comparing CCTA with an alternative noninvasive test. The relevant outcomes are OS, morbidity events, and resource utilization. Trials have shown similar patient outcomes, with faster patient discharges from the ED, and lower short-term costs. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have stable chest pain, intermediate-risk of CAD, and meeting guideline criteria for noninvasive testing (ie, intermediate-risk) who receive CCTA, the evidence includes studies of diagnostic accuracy of CCTA, randomized trials and observational studies comparing CCTA with alternative diagnostic strategies, and systematic reviews. The relevant outcomes are overall survival (OS), test accuracy, morbidity events, and resource utilization. Studies of diagnostic accuracy have shown that CCTA has higher sensitivity and similar specificity to alternative noninvasive tests. Although randomized trials have not shown the superiority of CCTA over other diagnostic strategies, results are consistent with noninferiority (ie, similar health outcomes) to other diagnostic strategies. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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For individuals who have suspected anomalous coronary arteries who receive CCTA, the evidence includes case series. The relevant outcomes are OS, test accuracy, morbid events, and resource utilization. Series have shown that CCTA can detect anomalous coronary arteries missed by other diagnostic modalities. Anomalous coronary arteries are rare, and formal studies to assess clinical utility are unlikely to be performed. In most situations, these case series alone would be insufficient to determine whether the test improves health outcomes. However, in situations where patient management will be affected by CCTA results (e.g., with changes in surgical planning), a chain of evidence indicates that health outcomes are improved. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**SUPPLEMENTAL INFORMATION**

**Practice Guidelines and Position Statements**

**American College of Cardiology Foundation et al**

The American College of Cardiology Foundation and several other medical societies (2012) issued joint guidelines for the management of patients with stable ischemic heart disease (see Table 1).

**Table 1. Guidelines on Management of Stable IHD**

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Recommendation</th>
<th>Class</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unknown</td>
<td>Able to exercise</td>
<td>IIb</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>&quot;CCTA might be reasonable for patients with an intermediate pretest probability of IHD who have at least moderate physical functioning or no disabling comorbidity.&quot;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unable to exercise</td>
<td>&quot;CCTA is reasonable for patients with a low-to-intermediate pretest probability of IHD who are incapable of at least moderate physical functioning or have disabling comorbidity.&quot;</td>
<td>IIa</td>
<td>B</td>
</tr>
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<td></td>
<td>&quot;CCTA is reasonable for patients with an intermediate pretest probability of IHD who a) have continued symptoms with prior normal test findings, or b) have inconclusive results from prior exercise or pharmacological stress testing, or c) are unable to undergo stress with nuclear MPI or echocardiography.&quot;</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>Known coronary disease</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Able to exercise</td>
<td>&quot;CCTA may be reasonable for risk assessment in patients with SIHD who are able to exercise to an adequate workload but have an uninterpretable ECG.&quot;</td>
<td>IIb</td>
<td>B</td>
</tr>
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<tr>
<td>Pharmacological stress imaging (nuclear MPI, echocardiography, or CMR) or CCTA is not recommended for risk assessment in patients with SIHD who are able to exercise to an adequate workload and have an interpretable ECG.&quot;</td>
<td>III</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>Unable to exercise</td>
<td>&quot;Pharmacological stress CMR is reasonable for risk assessment in patients with SIHD who are unable to exercise to an adequate workload regardless of interpretability of ECG.&quot;</td>
<td>IIa</td>
<td>B</td>
</tr>
<tr>
<td>CCTA can be useful as a first-line test for risk assessment in patients with SIHD who are unable to exercise to an adequate workload regardless of interpretability of ECG.&quot;</td>
<td>IIa</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>Unable to exercise</td>
<td>&quot;A request to perform either a) more than 1 stress imaging study or b) a stress imaging study and a CCTA at the same time is not recommended for risk assessment in patients with SIHD.&quot;</td>
<td>III</td>
<td>C</td>
</tr>
<tr>
<td>Regardless of patients’ ability to exercise</td>
<td>&quot;CCTA might be considered for risk assessment in patients with SIHD unable to undergo stress imaging or as an alternative to invasive coronary angiography when functional testing indicates a moderate- to high-risk result and knowledge of angiographic coronary anatomy is unknown.&quot;</td>
<td>IIb</td>
<td>C</td>
</tr>
</tbody>
</table>

CCTA: coronary computed tomography angiography; CMR: cardiac magnetic resonance; ECG: electrocardiography; IHD: ischemic heart disease; LOE: level of evidence; MPI: myocardial perfusion imaging; SIHD: stable ischemic heart disease.

The American College of Cardiology Foundation and other medical societies (2013) published appropriate use criteria for detection and risk assessment of stable ischemic heart disease. Coronary computed tomography angiography (CCTA) was considered appropriate
for:

- Symptomatic patients with intermediate (10%-90%) pretest probability of coronary artery disease and uninterpretable electrocardiogram (ECG) or inability to exercise
- Patients with newly diagnosed systolic heart failure
- Patients who have had a prior exercise ECG or stress imaging study with abnormal or unknown results
- Patients with new or worsening symptoms and normal exercise ECG.

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2016) has recommended CCTA as first-line testing for patients with stable angina if the clinical assessment indicates typical or atypical angina, or if the clinical assessment indicates non anginal chest pain but 12-lead resting ECG has been done and indicates ST-T changes or Q waves.

U.S. Preventive Services Task Force Recommendations

No U.S. Preventive Services Task Force recommendations for CCTA have been identified.

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


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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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<tr>
<td>September 2012</td>
<td>New policy</td>
<td>Policy updated with literature review, references 18, 19, 43, 45-48, 57-59 added, others removed. No change to policy statement.</td>
</tr>
<tr>
<td>March 2014</td>
<td>Replace policy</td>
<td>Policy updated with literature review through October 16, 2014; references 21, 23-24, 27, and 64 added; reference 65 updated. No change to policy statements.</td>
</tr>
<tr>
<td>March 2015</td>
<td>Replace policy</td>
<td>Policy updated with literature review through October 20, 2015; references 19 and 22-28 added. Medically necessary indication added for stable chest pain.</td>
</tr>
<tr>
<td>March 2016</td>
<td>Replace policy</td>
<td>Policy updated with literature review; references 12, and 18-19 added. Requirement for invasive angiography prior to computed tomography angiography removed from the policy statement on anomalous coronary arteries. Policy title changed to “Contrast-Enhanced Coronary Computed Tomography Angiography for Coronary Artery Evaluation”.</td>
</tr>
<tr>
<td>December 2017</td>
<td>Replace policy</td>
<td>Policy updated with literature review through July 21, 2017; references 29 and 31 added; reference 60 updated. Policy statements unchanged.</td>
</tr>
<tr>
<td>December 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through July 10, 2018; references 12, 14, 21-23, and 28-29 added. Policy statements unchanged.</td>
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### FEP 6.01.43 Contrast-Enhanced Computed Tomographic Angiography for Coronary Artery Evaluation

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<tr>
<td>December 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through June 26, 2019; references added. Policy statements unchanged.</td>
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