Coronary Artery Calcium Scoring

Policy Number: 2015M0095A  Effective Date: December 1, 2015

Table of Contents:

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
<th>Cross Reference Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>POLICY DESCRIPTION</td>
<td>2</td>
<td>Heart Transplantation, 2015M0048A</td>
</tr>
<tr>
<td>COVERAGE RATIONALE/CLINICAL CONSIDERATIONS</td>
<td>2</td>
<td>Cardiac Devices and Procedures for Occlusion of the Left Atrial Appendage, 2014M0061A</td>
</tr>
<tr>
<td>BACKGROUND</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>REGULATORY STATUS</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>CLINICAL EVIDENCE</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>APPLICABLE CODES</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>REFERENCES</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>POLICY HISTORY/REVISION INFORMATION</td>
<td>8</td>
<td></td>
</tr>
</tbody>
</table>

INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee’s specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
POLICY DESCRIPTION:

This policy describes the use of coronary artery calcium (CAC) scoring for the detection of subclinical coronary artery disease (CAD) by measuring an individual’s overall cardiac plaque burden. Performed using computed tomography (CT), CAC scoring has been investigated as a way to predict the risk of future CAD events, offering the possibility of improved risk stratification in adults who are asymptomatic for coronary artery disease.

COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:

Quantitative coronary artery calcium (CAC) scoring, either by electron beam computed tomography or multislice computed tomography (EBCT) or Helical CT or multi-slice spiral computed tomography scanner for use as a screening test or as a diagnostic test is considered EXPERIMENTAL AND INVESTIGATIVE due to insufficient published clinical evidence in peer-reviewed medical literature demonstrating the safety and/or impact on health outcomes or patient management.

Clinical Considerations:

Despite the potential benefits of coronary artery calcium screening, it is also subject to a number of limitations and therefore, there is disagreement on its value:

- Among asymptomatic patients with low Framingham risk score (< 5%), only a small number (less than 15%) of those with coronary artery calcification will have a cardiac event over the ensuing five years. Coronary artery calcification screening is unlikely to benefit low-risk or high-risk patients, and is not recommended.
- It has not been established that instituting or intensifying pharmacologic risk factor modification in asymptomatic patients with coronary artery calcification improves outcomes.
- The potential harm associated with false positives tests and radiation dose (especially with repeated testing) is not known.
- Providing patients with the results of coronary artery calcification testing may improve patient compliance with lifestyle changes and medications but results have been mixed.
- Cost effectiveness of coronary artery calcification screening has not been defined

The Framingham Risk Score (FRS) may be calculated by the risk assessment tool available at: [http://cvdrisk.nhlbi.nih.gov/](http://cvdrisk.nhlbi.nih.gov/).

BACKGROUND:

Coronary artery disease (CAD) is the leading cause of death in industrialized countries and was responsible for 1 in every 6 deaths in the United States in 2007. Most people are asymptomatic for CAD until they present with a serious cardiac event; 50% of men and 64% of women who die suddenly of CAD have no previous symptoms of the disease. Mechanisms to identify and stratify those at risk of developing CAD are necessary to determine the type and intensity of primary and secondary prevention strategies.

The Framingham Risk Score (FRS) is the standard first-step approach to risk stratification in the United States, with 3 categories of 10-year risk for CAD: low risk, defined as < 10% risk of experiencing a cardiac
event over the next 10 years; intermediate risk, defined as 10% to 20% risk; and high risk, defined as > 20% risk of experiencing a cardiac event over the ensuing 10 years. The majority of those screened (> 40% of the U.S. population) fall into the intermediate-risk category for which treatment decisions are uncertain. Strategies for further risk stratification are necessary to correctly reclassify intermediate-risk individuals into low- or high-risk categories.

Normally, the coronary arteries do not contain calcium. The presence of coronary artery calcium (atherosclerosis) has been shown to be strongly correlated with the extent of atherosclerotic plaque as well as the severity of CAD. Coronary artery calcium (CAC) can be considered a surrogate measure of a patient’s overall plaque burden and has been investigated for improved risk stratification, particularly in the intermediate FRS risk group. In recent decades, advances in imaging technology have allowed for the detection of CAC using noninvasive computed tomography (CT) in the form of either electron beam computed tomography (EBCT) also known as ultrafast computed tomography (UFCT) or helical or multislice detector computed tomography (MDCT) also known as multi-row detector. Software permits quantification of calcium area and density, which are translated into a coronary artery calcium score and used to score the risk of a cardiac event in the next five to ten years. EBCT and spiral CT or helical CT (multi-detector CT) for CAC measurement generally takes 10 to 15 minutes and requires only a few seconds of scanning time.

Coronary calcium levels can be expressed in many ways. The most widely used is the Agatston score, which is a weighted summed total of calcified coronary artery area observed on computed tomography. This value can be expressed as an absolute number, commonly ranging from 0 to 400. These values can be translated into age and sex-specific percentile values.

- 0 – no identifiable disease
- 1 to 99 – mild disease
- 100 to 399 – moderate disease
- > 400 – severe disease

Criteria for Pre-test Probability of CAD by Age, Gender and Symptoms

Pre-test probability of CAD can be assessed using the Framingham Risk Scoring Tool available at the following website, with low risk defined as a 10-year risk of less than 10%:

Or,

10-year pretest probability of atherosclerotic cardiovascular disease (ASCVD) can be estimated using Pooled Cohort equations from a downloadable spreadsheet and a web-based available at

REGULATORY STATUS:

1. U.S. FOOD AND DRUG ADMINISTRATION (FDA):

Coronary artery calcium (CAC) scoring is not in itself subject to FDA approval; however, computed tomography, which is the imaging modality used to perform CAC scanning, is subject to FDA
performance standards and regulations. The manufacturers of electronic radiation-emitting products sold in the United States are responsible for compliance with the Federal Food, Drug and Cosmetic Act (FFDCA), Chapter V, Subchapter C, Electronic Product Radiation Control. The manufacturers of computed tomography (CT) products are responsible for compliance with all applicable requirements of Title 21 Code of Federal Regulations (Subchapter J, Radiological Health) Parts 1000 through 1005. In addition, CT products must comply with radiation safety performance standards in Title 21 Code of Federal Regulations (Subchapter J, Radiological Health) Parts 1010 and 1020. In 2006, the FDA released guidance to inform CT equipment manufacturers that it intends to exercise enforcement discretion, under certain circumstances, with respect to a specific provision of the U.S. Federal performance standard for CT equipment. Specifically, the FDA does not intend to object to the use of an alternate measure of the computed tomography dose index (CTDI). CT equipment manufacturers who choose this alternative may substitute measured values of CTDI 100 for the required values of CTDI to meet the dose-information requirements of the U.S. Federal performance standard at 21 CFR 1020.33(c)(2) if the following conditions are met (CDRH, 2012):

- The manufacturer’s substituted values meet the definition of CTDI 100.
- The manufacturer clearly identifies the substituted values as CTDI 100 values rather than CTDI values.

FDA guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word “should” in FDA guidances means that something is suggested or recommended but not required (CDRH, 2011).

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):

CMS has not established a specific National Coverage Determination (NCD) that addresses CAC screening. However, CAC screening is not included in the cardiovascular screening examination that is covered every 5 years for Medicare beneficiaries and, therefore, is not a covered service (CMS, 2012).

3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):

Minnesota DHS does not have a policy statement regarding Coronary Artery Calcium Scoring in its Provider Manual or other specific provider references.

**CLINICAL EVIDENCE:**

Eighteen peer-reviewed articles reporting results of 11 distinct studies met the predefined inclusion criteria. One study was considered poor quality and was not selected for detailed review. Sixteen of the articles provided data relevant to whether CAC scoring adds predictive value to traditional global risk factor scoring such as the FRS, and one study examined the harms associated with cardiac imaging-related radiation exposure when CAC scoring is performed using CT. There was also one randomized trial that evaluated the impact of CAC scanning on clinical outcomes and risk assessment.
SUMMARY:
The available evidence suggests that coronary artery calcium (CAC) scoring adds incremental predictive value over traditional risk factor assessments such as the Framingham Risk Score (FRS), particularly among asymptomatic adults at intermediate risk of a coronary artery disease (CAD) event. Among 3 studies, 20% to 55% of those initially classified as intermediate risk were reclassified once CAC scores were considered. However, it is not yet known whether the addition of CAC scoring to standard risk factor assessment will improve patient-important outcomes (e.g., cardiac events). The one randomized trial comparing scanning with conventional risk factor analysis alone reported that CAC scanning was associated with some improvement in clinical risk factors for CAD, but there was no difference in adverse event rate between the scanned and non-scanned groups.

Despite the potential benefits of coronary artery calcium screening, it is also subject to a number of limitations and therefore, there is disagreement on its value:

- Among asymptomatic patients with low Framingham risk score (< 5%), only a small number (less than 15%) of those with coronary artery calcification will have a cardiac event over the ensuing five years. Coronary artery calcification screening is unlikely to benefit low-risk or high-risk patients, and is not recommended.
- It has not been established that instituting or intensifying pharmacologic risk factor modification in asymptomatic patients with coronary artery calcification improves outcomes.
- The potential harm associated with false positives tests and radiation dose (especially with repeated testing) is not known.
- Providing patients with the results of coronary artery calcification testing may improve patient compliance with lifestyle changes and medications but results have been mixed.
- Cost effectiveness of coronary artery calcification screening has not been defined

APPLICABLE CODES:

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-9 Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>414.0x*</td>
<td>Coronary atherosclerosis</td>
</tr>
<tr>
<td>434.91</td>
<td>Cerebral artery occlusion, with cerebral infarction</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>120.0</td>
<td>Unstable angina</td>
</tr>
<tr>
<td>125.10</td>
<td>Atherosclerosis without angina pectoris</td>
</tr>
<tr>
<td>125.9</td>
<td>Chronic ischemic heart disease, unspecified</td>
</tr>
<tr>
<td>166.01-166.9</td>
<td>Occlusion and stenosis of cerebral arteries, not resulting in cerebral infarction</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
</table>
Computed tomography, heart, without contrast material, with quantitative evaluation of coronary calcium

Unlisted cardiovascular service or procedure

CPT® is a registered trademark of the American Medical Association.

REFERENCES:


POLICY HISTORY:

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/12/2015</td>
<td>New policy 2015M0095A approved by the Medical Policy Committee.</td>
</tr>
<tr>
<td>10/22/2015</td>
<td>Reviewed and approved by the Quality Improvement Advisory and Credentialing Committee (QIACC).</td>
</tr>
<tr>
<td>11/01/2015</td>
<td>Published to UCare.org</td>
</tr>
</tbody>
</table>

QUESTIONS AND ANSWERS:

Q1: A1: 

ATTACHMENTS: