Contrast-Enhanced Computed Tomography Angiography (CTA) for Coronary Artery Evaluation

Policy # 00153
Original Effective Date: 07/15/2005
Current Effective Date: 09/02/2014

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider the use of contrast-enhanced computed tomographic angiography (CTA) for coronary artery evaluation to be eligible for coverage.

Patient Selection Criteria
Coverage eligibility will be considered when using at least a 64-slice multidetector row helical computed tomographic scanner for ANY of the following conditions:

- Evaluation of anomalous (native) coronary arteries in symptomatic patients when conventional angiography is unsuccessful or equivocal and when the results will impact treatment; OR
- Assessment of complex congenital heart disease including anomalies of coronary circulation, great vessels and cardiac chambers and valves; OR
- Evaluation of pulmonary vein anatomy prior to invasive radiofrequency ablation for atrial fibrillation; OR
- Evaluation of patients with chest pain who do not have known coronary artery disease (CAD) in the emergency room/emergency department setting; OR
- For exclusion of coronary artery disease (CAD) in patients with left ventricular ejection fraction < 55% and low or intermediate coronary heart disease risk (using standard methods of risk assessment such as Framingham or the American College of Cardiology [ACC] criteria) in patients whom coronary artery disease (CAD) has not been excluded as the etiology of the cardiomyopathy; OR
- Patients at intermediate coronary heart disease risk (using standard methods of risk assessment such as Framingham or American College of Cardiology [ACC] criteria) being evaluated for non-coronary artery cardiac surgery (including valvular and ascending aortic surgery) to avoid an invasive angiogram, where all of the necessary preoperative information can be obtained using cardiac computed tomography (CT); OR
- To evaluate patients with suspectful coronary artery disease (CAD) who have low or intermediate
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coronary heart disease risk (using standard methods of risk assessment such as Framingham or American College of Cardiology [ACC] criteria) and have had an equivocal myocardial perfusion imaging (MPI) or stress echo within the preceding 60 days; OR

- To evaluate patients with suspected coronary artery disease (CAD) who have a low coronary heart disease risk (using standard methods of risk assessment) who have had an abnormal myocardial perfusion imaging (MPI) or stress echo within the preceding 60 days suspected to be a false positive.

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers contrast-enhanced computed tomographic angiography (CTA) for coronary artery evaluation to be investigational for all other indications.

Background/Overview
Contrast-enhanced CTA is a noninvasive imaging test that requires the use of intravenously administered contrast material and high-resolution, high-speed CT machinery to obtain detailed volumetric images of blood vessels. It is a potential alternative to current diagnostic tests for cardiac ischemia, i.e., non-invasive stress testing and/or coronary angiography.

Contrast-enhanced CTA can be applied to image blood vessels throughout the body; however, for the coronary arteries, several technical challenges must be overcome to obtain high-quality diagnostic images. First, very short image acquisition times are necessary to avoid blurring artifacts from the rapid motion of the beating heart. In some cases, premedication with beta- blocking agents is used to slow the heart rate below approximately 60–65 beats per minute to facilitate adequate scanning, and electrocardiographic triggering or gating (retrospective or prospective) is used to obtain images during diastole when motion is reduced. Second, rapid scanning is also helpful so that the volume of cardiac images can be obtained during breath-holding. Third, very thin sections (1 mm or less) are important to provide adequate spatial resolution and high-quality 3D reconstruction images.

Volumetric imaging permits multiplanar reconstruction of cross-sectional images to display the coronary arteries. Curved multiplanar reconstruction and thin-slab maximum intensity projections provide an overview of the coronary arteries, and volume-rendering techniques provide a 3D anatomical display of the exterior of the heart. Two different CT technologies can achieve high-speed CT imaging. Electron beam CT (EBCT, also known as ultrafast CT) uses an electron gun rather than a standard x-ray tube to generate x-rays, thus permitting very rapid scanning, on the order of 50–100 milliseconds per image. Helical CT scanning (also referred to as spiral CT scanning) also creates images at greater speed than conventional CT by continuously rotating a standard x-ray tube around the patient so that data are gathered in a continuous spiral or helix rather than as individual slices. Helical CT is able to achieve scan times of 500 milliseconds or less per image, and use of partial ring scanning or post-processing algorithms may reduce the effective scan time even further.
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Multidetector row helical CT (MDCT) or multislice CT scanning, is a technologic evolution of helical CT, which uses CT machines equipped with an array of multiple x-ray detectors that can simultaneously image multiple sections of the patient during a rapid volumetric image acquisition. Multidetector row helical CT machines currently in use have 64 or more detectors.

A variety of noninvasive tests are used in the diagnosis of coronary artery disease (CAD). They can be broadly classified as those that detect functional or hemodynamic consequences of obstruction and ischemia (exercise treadmill testing, MPI, stress echo with or without contrast), and others that identify the anatomic obstruction itself (coronary CTA and coronary magnetic resonance imaging [MRI]). Functional testing involves inducing ischemia by exercise or pharmacologic stress and detecting its consequences. However, not all patients are candidates. For example, obesity or obstructive lung disease can make obtaining echocardiographic images of sufficient quality difficult. Conversely, the presence of coronary calcifications can impede detecting coronary anatomy with coronary CTA. Accordingly, some tests will be unsuitable for particular patients.

Evaluation of obstructive CAD involves quantifying arterial stenoses to determine whether significant narrowing is present. Lesions with greater than 50% to 70% diameter stenosis accompanied by symptoms are generally considered significant and often result in revascularization procedures. It has been suggested that coronary CTA may be helpful to rule out the presence of CAD and to avoid invasive coronary angiography (ICA) in patients with a low clinical likelihood of significant CAD. Also of note is the interest in the potential important role of non-obstructive plaques (i.e., those associated with < 50% stenosis) because their presence is associated with increased cardiac event rates. Coronary CTA can also visualize the presence and composition of these plaques and quantify the plaque burden better than conventional angiography, which only visualizes the vascular lumen. Plaque presence has been shown to have prognostic importance.

The information sought from angiography after coronary artery bypass graft (CABG) surgery may depend on the length of time since surgery. Bypass graft occlusion may occur during the early postoperative period; whereas, over the long term, recurrence of obstructive CAD may occur in the bypass graft, which requires a similar evaluation as CAD in native vessels.

Congenital coronary arterial anomalies (i.e., abnormal origination or course of a coronary artery) that lead to clinically significant problems are relatively rare. Symptomatic manifestations may include ischemia or syncope. Clinical presentation of anomalous coronary arteries is difficult to distinguish from other more common causes of cardiac disease; however, an anomalous coronary artery is an important diagnosis to exclude, particularly in young patients who present with unexplained symptoms (e.g., syncope). There is no specific clinical presentation to suggest a coronary artery anomaly.

Coronary CTA has several important limitations. The presence of dense arterial calcification or an intracoronary stent can produce significant beam-hardening artifacts and may preclude a satisfactory study. The presence of an uncontrolled rapid heart rate or arrhythmia hinders the ability to obtain diagnostically satisfactory images. Evaluation of the distal coronary arteries is generally more difficult than visualization of the proximal and mid-segment coronary arteries due to greater cardiac motion and the smaller caliber of
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coronary vessels in distal locations.

Radiation delivered with current generation scanners utilizing reduction techniques (prospective gating and spiral acquisition) has declined substantially—typically to under 10 mSv. For example, an international registry developed to monitor coronary CTA radiation recently reported a median 2.4 mSv (interquartile range, [IQR]: 1.3 to 5.5) exposure. In comparison, radiation exposure accompanying rest-stress perfusion imaging ranges varies according to isotope used—approximately 5 mSv for rubidium-82 (PET), 9 mSv for sestamibi (SPECT), 14 mSv for F-18 FDG (PET), and 41 mSv for thallium; during diagnostic ICA, approximately 7 mSv will be delivered. Electron beam CT using electrocardiogram (ECG) triggering delivers the lowest dose (approximately 0.7 to 1.1 mSv with 3-mm sections). Any cancer risk due to radiation exposure from a single cardiac imaging test depends on age (higher with younger age at exposure) and gender (greater for women). Empirical data suggest that every 10 mSv of exposure is associated with a 3% increase in cancer incidence over 5 years.

Table 1: Determination of Pretest Probability for Coronary Disease Based on Age, Gender, and Symptoms (Source: American College of Cardiology [ACC] Criteria for Pretest Probability of Coronary Artery Disease [CAD]). The following risk assessment may be used to determine pre-test probability of CAD.

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Gender</th>
<th>Typical/Definite Angina Pectoris</th>
<th>Atypical/Probable Angina Pectoris</th>
<th>Nonanginal Chest Pain</th>
<th>Asymptomatic</th>
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</thead>
<tbody>
<tr>
<td>30 – 39</td>
<td>Men</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Very low</td>
<td>Very low</td>
<td>Very low</td>
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<tr>
<td>40 – 49</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
<td>Very low</td>
</tr>
<tr>
<td>50 – 59</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
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<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very low</td>
</tr>
<tr>
<td>60 – 69</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>High</td>
<td>Intermediate</td>
<td>Low</td>
<td>Low</td>
</tr>
</tbody>
</table>

High: Greater than 90% pre-test probability  
Intermediate: Between 10% and 90% pre-test probability  
Low: Between 5% and 10% pre-test probability  
Very low: Less than 5% pre-test probability

Angina: As defined by the American College of Cardiology (ACC)/American Heart Association (AHA)

Typical Angina (Definite): 1.) Substernal chest pain or discomfort that is 2.) Provoked by exertion or emotional stress and 3.) Relieved by rest and/or nitroglycerine.

Atypical Angina (Probable): Chest pain or discomfort that lacks one of the characteristics of definite or typical angina.

Non-Anginal Chest Pain: Chest pain or discomfort that meets one or none of the typical angina characteristics.
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Rationale/Source
This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration (FDA) approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

References

Coding
The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®), copyright 2013 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

<table>
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<th>Code Type</th>
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<td>CPT</td>
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<tr>
<td>HCPCS</td>
<td>No codes</td>
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<tr>
<td>ICD-9 Diagnosis</td>
<td>413.9, 414.00 thru 414.9, 440.0 thru 440.9</td>
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<tr>
<td>ICD-9 Procedure</td>
<td>No codes</td>
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Policy History

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<th>07/15/2005</th>
<th>Current Effective Date:</th>
<th>09/02/2014</th>
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<tr>
<td>06/07/2005</td>
<td>Medical Director review</td>
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<td>07/15/2005</td>
<td>Managed Care Advisory Council approval</td>
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<td>07/07/2006</td>
<td>Format revision including addition of FDA and or other governmental regulatory approval and Rationale/source. Coverage eligibility unchanged.</td>
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<td>01/23/2008</td>
<td>Medical Policy Committee approval. Eligible for coverage statement added for CTA evaluation of anomalous (native) coronary arteries in symptomatic patients when conventional angiography is unsuccessful or equivocal and when the results will impact treatment.</td>
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<td>Medical Policy Committee approval. No change to coverage eligibility.</td>
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<td>Medical Policy Implementation Committee approval. Added coverage for evaluation of patients in the emergency room without known coronary artery disease and acute chest pain.</td>
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<td>03/20/2013</td>
<td>Medical Policy Implementation Committee approval. Replaced the 1st eligible for coverage criteria bullet to match the one from the 2008 policy. Added four new criteria bullets to be eligible for coverage. Included examples of standard methods of risk assessment such as Framingham or ACC criteria in the Patient Selection Criteria of this policy. Added a table to the Background/Overview section on the determination of pretest probability for coronary artery disease.</td>
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Next Scheduled Review Date: 07/2015

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

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A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
   1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
   2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
   3. reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. in accordance with nationally accepted standards of medical practice;

B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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