Computed Tomography to Detect Coronary Artery Calcification

Policy # 00031
Original Effective Date: 10/21/2002
Current Effective Date: 12/17/2016

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.

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 the use of electron beam computed tomography (EBCT) or spiral computed tomography (CT) to detect coronary artery calcification to be investigational.*

Background/Overview
Several types of fast CT imaging, including EBCT 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.

Coronary artery calcium has been recognized to be associated with CAD on the basis of anatomic studies for decades. The development of fast CT scanners has allowed the measurement of CAC in clinical practice. Coronary artery calcium has been evaluated in several clinical settings. The most widely studied indication is for the use of CAC in the prediction of future risk for CAD in patients with subclinical disease, with the goal of instituting appropriate risk-reducing therapy (eg, statin treatment; lifestyle modifications) to improve outcomes. In addition, CAC has been evaluated in patients with symptoms potentially consistent with CAD, but in whom a diagnosis is unclear.

Both EBCT (also known as ultrafast CT) and spiral CT scanning may be valued as an alternative to conventional CT scanning due to their faster throughput, their speed of image acquisition also permits unique imaging of the moving heart. For example, the rapid image acquisition time virtually eliminates motion artifact related to cardiac contraction, permitting visualization of the calcium in the epicardial coronary arteries. Electron beam computed tomography software permits quantification of calcium area and density, which are translated into calcium scores. Calcium scores have been investigated as a technique for detecting coronary artery calcification, both as a diagnostic technique in symptomatic patients to rule out an atherosclerotic etiology of symptoms or, in asymptomatic patients, as an adjunctive method for risk stratification for CAD.

EBCT and multidetector computed tomography were initially the primary fast CT methods for measurement of CAC. A fast CT study for CAC measurement generally takes 10 to 15 minutes and requires only a few seconds of scanning time. More recently, computed tomography angiography (CTA) has been used to assess coronary calcium. Because of the basic similarity between EBCT and CTA in measuring coronary calcium, it is expected that CTA provides information on coronary calcium that is similar to EBCT.
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CT scan–derived coronary calcium measures have been used to evaluate coronary atherosclerosis. Coronary calcium is present in coronary atherosclerosis, but the atherosclerosis detected may or may not be causing ischemia or symptoms. Coronary calcium measures may be correlated with the presence of critical coronary stenoses or serve as a measure of the patient's proclivity toward atherosclerosis and future coronary disease. Thus, it could serve as a variable to be used in a risk assessment calculation to determine appropriate preventive treatment in asymptomatic patients. Alternatively, in other clinical scenarios, it might help determine whether there is atherosclerotic etiology or component to the presenting clinical problem in symptomatic patients, thus helping to direct further workup for the clinical problem. In this second scenario, a calcium score of 0 usually indicates that the patient's clinical problem is unlikely to be due to atherosclerosis and that other etiologies should be more strongly considered. In neither case does the test actually determine a specific diagnosis. Most clinical studies have examined the use of coronary calcium for its potential use in estimating the risk of future coronary heart disease events.

Coronary calcium levels can be expressed in many ways. The most common method is the Agatston score, which is a weighted summed total of calcified coronary artery area observed on CT. 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. Different imaging methods and protocols will produce different values based on the specific algorithm used to create the score, but the correlation between any 2 methods appears to be high, and scores from 1 method can be translated into scores from a different method.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Many models of CT devices, including EBCT and other ultrafast CT devices, have been cleared for marketing by FDA through the 510(k) process. FDA product code: JAK.

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination (NCD).

Rationale/Source
This policy is based, in part, on a 1998 Technology Evaluation Center (TEC) Assessment.

Coronary Calcium for Coronary Disease Risk Stratification
Many prospective studies have provided evidence for the predicative capacity of calcium scores in addition to assessment of traditional risk factors for coronary heart disease (CHD) among asymptomatic subjects. This review focuses on relevant large prospective studies.

In 2015, Pursnani et al used data from the offspring and third-generation cohorts of the Framingham Heart Study, including 2435 statin-naive individuals, to evaluate the association of CAC scores as a predictive factor (beyond typical risk factors) with incident CAD. Coronary artery calcium scores greater than 100 and greater than 300 were associated with increased risk of cardiac events in both statin eligible and noneligible subjects. In a study of 1029 asymptomatic adults with at least 1 coronary risk factor, Greenland et al showed that a calcium score of greater than 300 predicted increased risk of cardiac events within...
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Framingham risk categories. A study by Arad et al showed similar findings in a population-based sample of 1293 subjects who had both traditional risk factors and calcium scores evaluated at baseline. A study by Taylor et al evaluated the association between the Framingham risk scores and calcium scores in a young military population (mean age, 43 years). Although only 9 acute coronary events occurred, calcium scores were associated with risk of events while controlling for the risk score. LaMonte et al also analyzed the association between calcium scores and CHD events in 10,746 adults. In this study, coronary risk factors were self-reported. During a mean follow-up of 3.5 years, 81 CHD events occurred. Like other studies, the relation between calcium scores and CHD events remained after adjusting for other risk factors. Budoff et al evaluated the association between coronary calcium scores and CHD events during 5-year follow-up of 2232 adults from the Multiethnic Study of Atherosclerosis (MESA), a prospective cohort study to evaluate cardiac risk factors, and 3119 subjects from the Heinz Nixdorf RECALL (Risk factors, Evaluation of Coronary Calcium and Lifestyle Factors) study. Increasing Agatston score was associated with increased risk of CHD. In the MESA study, compared with a CAC score of 0, having a score greater than 400 was associated with a hazard ratio (HR) for CHD of 3.31 (95% confidence interval [CI], 1.12 to 9.8) after adjusting for CHD risk factors; a score ranging from 100 to 399 was associated with a hazard ratio of 3.27 (95% CI, 1.19 to 8.95). In the RECALL study, the HR for CHD was 2.96 (95% CI, 1.22 to 7.19). Lower CAC scores were not significantly associated with CHD after adjusting for other risk factors. Other studies have shown similar findings.

Additional analysis of data from the MESA study found that CAC is associated with CHD events among individuals at either high or low CHD risk on the basis of traditional risk factors. Gibson et al used data from the MESA study to evaluate the association between CAC and incidence of cerebrovascular events, including all strokes and transient ischemic attacks (TIAs). Over an average of 9.5 years of follow-up, 234 cerebrovascular events occurred (3.5%). Having an elevated CAC was independently predictive of both cerebrovascular events and stroke (HR=1.70; 95% CI, 1.24 to 2.35; p=0.001; HR=1.59; 95% CI, 1.11 to 2.07; p=0.01, respectively). Blaha et al also used data from MESA to demonstrate that a CAC score of 0 was associated with the highest reclassification in cardiovascular risk compared with other risk markers (eg, high-sensitivity C-reactive protein [hs-CRP]).

Additional studies have defined how the incorporation of calcium scores into risk scores changes risk prediction. In a study by Polonsky et al, incorporation of calcium score into a risk model resulted in more subjects (77% vs 66%) being classified in either high-risk or low-risk categories. The subjects who were reclassified to high risk had similar risk of CHD events as those who were originally classified as high risk. A study by Elias-Smale et al showed similar findings; reclassification of subjects occurred most substantially in the intermediate-risk group (5%-10% 5-year risk) where 56% of persons were reclassified.

Some studies have evaluated whether CAC score changes CHD risk prediction in addition to or compared with other types of noninvasive testing in conjunction with clinical risk scores. Chang et al prospectively evaluated whether CAC score added incremental predictive value to exercise treadmill testing and stress myocardial perfusion single-photon emission computed tomography testing in predicting risk of cardiac events, defined as a composite of cardiac death, nonfatal myocardial infarction (MI), and the need for coronary revascularization, in a cohort of 988 asymptomatic or symptomatic low-risk patients without known
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CHD. Over a median follow-up of 6.9 years, the rate of cardiac events was 11.2% (1.6% per year). Annual event rates were higher in patients with CAC scores above 400 compared with those with CAC score of less than or equal to 10 (3.7% vs 0.6% per year, p<0.001). The addition of CAC score to risk stratification based on Framingham risk score improved risk prediction.

Numerous studies have also evaluated the predictive ability of coronary calcium using CT angiography. These studies have included different populations, such as patients with or without risk factors or patients with an intermediate risk of CAD. Similar to studies that use EBCT, these studies have demonstrated that calcium scores derived from CT angiography provide incremental predictive information for the overall risk of CAD, as compared with coronary angiography and for the future occurrence of major cardiac events.

Impact on Cardiac Risk Factor Profiles in Practice
While epidemiologic studies suggest that CAC scoring may be associated with future CHD risk, this does not, by itself, demonstrate that the use of CAC scoring improves clinical outcomes.

There have been a small number of randomized, controlled trials (RCTs) of the impact of CAC measurements on cardiac risk factors. In 2012, Whelton et al published a meta-analysis of RCTs that evaluated the impact of coronary calcium scores on cardiac risk profiles and cardiac procedures. There were 4 trials identified with a total of 2490 participants; the individual trials ranged in size from 50 to 1934 patients. The authors pooled data from 4 trials on the impact of calcium scores on blood pressure, 3 on the impact on low-density lipoprotein, and 2 on the impact on high-density lipoprotein. Pooled analysis did not show a significant change in any of these parameters as a result of calcium scores. Similarly, in 4 studies that looked at the rates of smoking cessation following calcium scores, there was no significant change found. There were 2 studies that included rates of coronary angiography and 2 studies that included rates of revascularization. Pooled analysis of these studies did not show a significant change following measurement of coronary calcium.

Two RCTs representative of this evidence are discussed further here. O'Malley et al randomized 450 subjects to receive EBCT or not and assessed outcomes 1 year later for change in Framingham Risk Score. Thus, EBCT was to be used as a guide to refine risk in patients and possibly provide motivation for behavioral change. The study was not powered for clinical end points. Electron beam computed tomography did not produce any benefits in terms of a difference in Framingham risk score at 1 year.

An RCT was published in 2011 evaluating the impact of CT scanning for CAC on cardiac risk factors. A total of 2137 healthy subjects were randomized to CT scanning or no CT scanning and followed for 4 years. At baseline, both groups received 1 session of risk factor counseling by a nurse practitioner. The primary outcome was change in 12 different cardiac risk profile measures, including blood pressure, lipid and glucose levels, weight, exercise, and the Framingham risk score. At the 4-year follow-up, there was differential dropout among the groups, with 88.2% of follow-up in the scan group versus 81.9% in the no-scan group. Results demonstrated differences in 4 of the 12 risk factor measurements between groups: systolic blood pressure, low-density lipoprotein, waist circumference, and mean Framingham risk score.
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This trial highlights the potential benefit of CAC screening in modifying cardiac risk profile but is not definitive in demonstrating improved outcomes. Limitations of this study include different intensity of interventions between groups and differential dropout. It is possible that the small differences reported in the trial were the result of bias from these methodologic limitations. In addition, this trial does not compare the impact of other types of risk factor intervention, most notably more intensive risk factor counseling. Finally, the generalizability of the findings is uncertain given that this was a volunteer population that may have been highly motivated for change.

A number of studies have evaluated whether the use of CAC in asymptomatic patients is associated with subsequent behavioral change particularly related to risk factor reduction or medication adherence. Mamudu et al conducted a systematic review of studies evaluating the effects of CAC screening on behavioral modification, risk perception, and medication adherence in asymptomatic adults, which included 15 studies, 3 RCTs, and 12 observational studies. The systematic review primarily provided descriptive results of the studies given the lack of standardization across studies in terms of CAC measures and outcome variables. Thirteen of the 15 studies, including 2 of the RCTs, reported increased medication adherence in CAC-screened patients. An example of one of the observational studies included in the Mamudu et al systematic review was reported by Johnson et al, who assessed the association between CAC score and subsequent health behavior change. The study included a convenience sample of 174 adults with CHD risk factors who underwent CAC scoring. The authors found no significant change in risk perception measured by the Perception of Risk of Heart Disease Scale scores between groups (CAC score, 0, 1-10, 11-100, 101-400, >400), with the exception of a small increase in the moderate-risk group (CAC score, 101-400) from 55.5 to 58.7 (p=0.004). All groups demonstrated increases in health-promoting behavior over time.

Shreibati et al used Medicare claims data to compare clinical outcomes and cardiac testing utilization for patients who had CAC scoring with patients who had high-sensitivity C-reactive protein (hs-CRP) testing or lipid screening. The study included 4184 patients who had CAC who were propensity-score matched to 261,356 patients who had hs-CRP and 118,093 patients who had lipid screening. CAC testing was associated with increased rates of noninvasive cardiac testing within 180 days (HR=2.22; 95% CI, 1.68 to 2.93; p<0.001 vs hs-CRP; HR=4.30; 95% CI, 3.04 to 6.06; p<0.001 vs lipid screening). It was also associated with increased rates of coronary angiography (HR=3.54; 95% CI, 1.91 to 6.55; p<0.001 vs hs-CRP; HR=4.23; 95% CI, 2.31 to 7.74; p<0.001). Overall rates of the composite outcome of death, MI, or stroke were low, but event-free survival was higher in patients who underwent CAC compared with those who had hs-CRP (94.4% vs 92.7%, p=0.008).

Section Summary
Multiple prospective studies have found that CAC scoring is associated with future risk of CHD events. CAC scores likely add to the predictive ability of clinical risk prediction models. However, relevant studies enrolled different populations, assessed different traditional risk factors, and assessed different coronary disease outcomes. Different calcium score cutoffs were analyzed in these studies. Given the variation across studies, the magnitude of increased risk conferred by a given calcium score is still uncertain. Some evidence from cohort studies has also suggested that CAC scoring may be associated with stroke risk. Studies that used
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CAC scoring in asymptomatic patients have reported mixed findings whether CAC testing leads to improved cardiovascular risk profiles or improvements in other meaningful clinical outcomes. The largest meta-analysis did not find significant improvements in cardiac risk profiles or changes in cardiac procedures with the use of CAC scoring.

**Coronary Calcium for Ruling Out Atherosclerotic Etiology of Disease in Symptomatic Patients**

In certain clinical situations, such as patients presenting with chest pain or other symptoms, it is uncertain whether the symptoms are potentially due to CHD. Coronary calcium measurement has been proposed as a method that can rule out CHD in certain patients if the coronary calcium value is zero. Because coronary disease can only very rarely occur in the absence of coronary calcium, the presence of any coronary calcium can be a sensitive but not specific test for coronary disease. False positives occur because the calcium may not be causing ischemia or symptoms. The absence of any coronary calcium can be a specific test for the absence of coronary disease and direct the diagnostic workup toward other causes of the patient’s symptoms. In this context, coronary calcium measurement is not used to make a positive diagnosis of any kind but as a diagnostic “filter” used to rule out an atherosclerotic cause for the patient's symptoms.

For example, Yerramasu et al reported results of a prospective study to assess an evaluation algorithm including CAC scoring for patients presenting to a rapid access chest pain clinic with stable chest pain possibly consistent with CHD. Three hundred patients presenting with acute chest pain to 1 of 3 chest pain clinics underwent CAC scoring. If the CAC score was 1000 or more Agatston units invasive coronary angiography (ICA) was performed, and if the CAC score was less than 1000, coronary CT angiography (CCTA) was performed. All patients with a CAC of zero and low pretest likelihood of CHD had no obstructive Cardiovascular Health Study (CHS) on CCTA and were event-free during follow up. Of the 18 patients with CAC score from 400 to 1000, 17 (94%) had greater than 50% obstruction on subsequent CCTA and were referred for further evaluation, 14 (78%) of whom had obstructive CHD. Of 15 patients with CAC score 1000 or more and who were referred for coronary angiography, obstructive CHD was present in 13 (87%). This study suggests that CAC can be used in the acute chest pain setting to stratify decision making for further testing.

In a study by Laudon et al in the emergency department setting, 51% (133/263) patients with chest pain and low-to-moderate probability of CAD had calcium scores of zero. One of these patients was found to actually have coronary disease. The others were presumed to not have coronary disease, and it is claimed that these patients could have been safely discharged from the emergency department. However, the study is not rigorous in its methods regarding the alternative workup of potential CAD in the emergency department or in the long-term follow-up of patients.

In addition to studies that use coronary calcium scores to rule out CHD among patients presenting with symptoms potentially consistent with CHD, coronary calcium scoring has also been evaluated to rule in or out potential CHD in symptomatic patients before ICA or stress nuclear imaging. The 2007 expert consensus guidelines from the American College of Cardiology and the American Heart Association state that CAC may serve “as a filter prior to ICA or stress nuclear imaging” but that “prognostic studies of CAC in symptomatic patients have generally been limited by biased samples (eg, patients referred for ICA) and
small numbers of hard outcome events."

Since the 2007 consensus statement, several studies have addressed the use of CAC scoring as part of a management strategy for patients presenting with symptoms possibly consistent with CHD. In 2015, Pursnani et al published results from a subanalysis of the ROMICAT II trial evaluating the incremental diagnostic value of CAC scoring in addition to CCTA in low-intermediate risk patients presenting to the ED with symptoms suggesting acute coronary syndrome (ACS). The ROMICAT II trial randomized patients with possible ACS to either CCTA as part of an initial evaluation or to the standard ED evaluation strategy, as directed by local caregivers. As part of the protocol, all patients undergoing CCTA had a CAC scan; the present analysis included 473 patients who underwent both CCTA and CAC scanning. Among these patients, the ACS rate (defined as unstable angina and MI during the index hospitalization) was 8% (n=38). Patients with lower CAC scores were less likely to have a discharge diagnosis of ACS. Among 253 patients with CAC=0, there were 2 patients with ACS (0.8%; 95% CI, 0.1 to 2.8%). Receiver operating characteristic (ROC) curve analysis was used to predict the risk of ACS by CAC greater than 0, continuous CAC score, CCTA results, and combined CAC and CCTA score. The optimal cut point of CAC for ACS detection was 22 (C statistic, 0.81), with 318 patients (67%) having CAC less than 22. All CCTA strategies had high sensitivity for ACS detection, without significant differences across stenosis thresholds. CAC was inferior to CCTA for predicting ACS (C statistic, 0.86 vs 0.92; p=0.03). The addition of CAC score to CCTA (ie, using selective CCTA only for patients with CAC score of >22 or >0) did not significantly improve the detection of ACS (CAC+CCTA C statistic, 0.93 vs CCTA C statistic, 0.92; p=0.88). Overall, this study suggests that CAC scoring does not provide incremental value beyond CCTA in predicting likelihood of ACS in a low-intermediate risk population presenting to the ED.

In 2014, Hulten et al published results from a retrospective cohort study among symptomatic patients without a history of CHD to evaluate the accuracy of CAC for excluding coronary stenosis among symptomatic patients, using CCTA as the criterion standard. The study included 1145 patients who had symptoms possibly consistent with CHD who underwent a noncontrast CAC score and a contrast enhanced CCTA from 2004 to 2011. For detection of greater than 50% stenosis, CAC had a sensitivity of 98% and specificity of 55%, corresponding to a negative predictive value of 99%. For prediction of cardiovascular death or MI, the addition of either or both CAC or CCTA to a clinical prediction score did not significantly increase prognostic value.

In another retrospective study, Chaikriangkrai et al evaluated whether CAC added incremental predictive value to CCTA for predicting coronary artery stenosis in 805 symptomatic patients without known CHD. CAC score was significantly associated with the presence of coronary artery stenosis on CCTA. Both CAC score and the presence of CCTA stenosis were significantly associated with rates of major adverse cardiac events, including cardiac death, nonfatal MI, and late coronary revascularization. Patients with more than 50% stenosis on CCTA had higher rates of major adverse cardiac events, compared with those with normal CCTA (4.5% vs 0.1%, p<0.001) and with those with less than 50% stenosis (4.5% vs 1.4%, p=0.002). Those with a CAC of more than 400 had higher rates of major adverse cardiac events than those with a score between 1 and 100 (4.2% vs 1.4%, p=0.014) and those with a score of 0 (4.2% vs 0% p<0.001). The addition of CAC score to a risk prediction model for major adverse cardiac events, which included clinical
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risk factors and CCTA stenosis, significantly improved the model's predictive performance (108 vs 70; p=0.019).

Ten Kate et al conducted a prospective study to evaluate the accuracy of cardiac CT, including CAC scoring with or without CCTA, in distinguishing heart failure due to CAD from heart failure due to non-CAD causes. Data on the predictive ability of a negative CAC in ruling out CAD was also included. The study included 93 symptomatic patients with newly diagnosed heart failure of unknown etiology, all of whom underwent CAC scoring. Those with a CAC score of greater than 0 underwent CCTA, and if the CCTA was positive for CAD (>20% luminal diameter narrowing), ICA was recommended. Forty-six percent of patients had a CAC score of zero. At follow-up of mean duration 20 months, no patient with a CAC score of zero had a myocardial infarction, underwent percutaneous coronary intervention, had a coronary artery bypass graft, or had signs of CAD.

Dharampal et al retrospectively evaluated a cohort of 1975 symptomatic patients who underwent clinical evaluation and CAC scoring and CCTA or ICA. The primary outcome was obstructive CAD (≥50% stenosis) on ICA or CCTA (if ICA was not done). The authors evaluated the net reclassification improvement with the addition of CAC score to a clinical prediction model for patients who had an intermediate probability of CHD (10%-90%) after clinical evaluation based on chest pain characteristic, age, gender, risk factors, and electrocardiogram. Discrimination of CAD was significantly improved by adding the CAC score to the clinical evaluation (area under the curve, 0.80 vs 0.89, p<0.001).

In 2015, in a pilot study, Korley et al described a diagnostic strategy of low- to high-sensitivity troponin I (hsTnI) and CAC to identify individuals at low risk of CAD presenting with suspected ACS, and in whom CCTA could be avoided. The authors reported on 314 patients who presented to an ED with suspected ACS. Using a strategy of no further testing for patients with undetectable hsTnI while obtaining CAC scores for patients with detectable but nonincreased hsTnI and CTA in subjects with an Agatston score greater than 0 yielded an NPV of 100.0% (95% CI, 98.2% to 100%) for significant CAD.

Section Summary
A number of studies suggest that CAC scoring could be used to rule in or rule out CHD, particularly regarding decisions about further invasive imaging. However, relatively few studies have employed a prospective design. Further studies need to be conducted to address some of the potential barriers to such an approach, including whether performing CAC scoring in symptomatic patients delays diagnosis or intervention and whether the net effect of CAC scoring is to increase or decrease invasive testing.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this policy are listed in Table 1.

Table 1. Summary of Key Trials

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Evaluation Program

NCT: national clinical trial.
* Denotes industry-sponsored or cosponsored trial.

Clinical Input Received Through Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2008 Input
In response to requests, input was received through 2 physician specialty societies and 4 academic medical centers on this policy (the version approved in July 2008) in November 2008. Most of those providing input agreed with the conclusions of this policy (investigational) as approved in July 2008.

2011 Input
Clinical input received in 2011 was mixed regarding the investigational status of CAC screening. Input was received from 7 sources, 5 academic medical centers, and 2 specialty societies. Four of the 7 reviewers agreed with the investigational status, while 3 dissented. The dissenters primarily cited evidence on the accuracy of scanning for risk prediction of CAD.

Summary
For individuals who are asymptomatic with risk of CAD who receive CAC scoring, the evidence includes multiple prospective studies. Relevant outcomes include overall survival, test accuracy and validity, morbid events, resource utilization, 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, evidence from high-quality studies that has demonstrated that the use of CAC score measurement in clinical practice leads to changes in patient management or in individual risk behaviors that improve cardiac outcomes is lacking. At least 1 RCT has suggested that the use of CAC score measurement in clinical practice may be associated with improved cardiac risk profiles, but an association between CAC score measurement with improved outcomes has not yet been demonstrated in other studies. 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 include overall survival, test accuracy and validity, morbid events, resource utilization, 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 retrospective studies has suggested that negative results on CAC scoring rule out CAD with good reliability, and at least 1 prospective study has suggested that CAC score can be used in an emergency setting to stratify patients for further testing. However, 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.
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demonstrate that use of calcium scores improves the efficiency or accuracy of the diagnostic workup of symptomatic patients, rigorous studies that define exactly how CAC scores are used in combination with other tests in the triage of patients would be necessary. The evidence is insufficient to determine the effects of the technology on health outcomes.

References
2. 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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40. Taylor AJ, Cerqueira M, Hodgson JM, et al. ACCF/SCT/ACR/AHA/ASE/NASCET/SCAI/SOMR. 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.
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10/19/2002 Medical Policy Committee review
10/21/2002 Managed Care Advisory Council approval
10/05/2004 Medical Director review
11/16/2004 Medical Policy Committee review. Format revision. No substance change to policy
11/29/2004 Managed Care Advisory Council approval
07/07/2006 Format revision. including, addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
11/01/2006 Medical Director review
11/05/2008 Medical Director review
11/18/2008 Medical Policy Committee approval. No change to coverage eligibility.
01/01/2010 Coding revision.
11/04/2010 Medical Policy Committee approval
11/16/2010 Medical Policy Implementation Committee approval. No change to coverage eligibility.
02/01/2011 Coding revision
11/03/2011 Medical Policy Committee approval
11/16/2011 Medical Policy Implementation Committee approval. No change to coverage eligibility.
11/01/2012 Medical Policy Committee approval
11/28/2012 Medical Policy Implementation Committee approval. No change to coverage eligibility.
11/07/2013 Medical Policy Committee review
11/20/2013 Medical Policy Implementation Committee approval. Title changed from "Electron Beam/Spiral Computed Tomography to Detect Coronary Calcification" to "Computed Tomography to Detect Coronary Calcification". Coverage eligibility unchanged.
11/06/2014 Medical Policy Committee review
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/29/2015 Medical Policy Committee approval
11/16/2015 Medical Policy Implementation Committee approval. Title change. No change to coverage eligibility. Title change.
11/03/2016 Medical Policy Committee approval
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01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
Next Scheduled Review Date: 11/2017

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 2015 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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*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:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. 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 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.

‡ Indicated trademarks are the registered trademarks of their respective owners.
Computed Tomography to Detect Coronary Artery Calcification

Policy # 00031
Original Effective Date: 10/21/2002
Current Effective Date: 12/17/2016

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.