CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject **Electron Beam Computed Tomography (EBCT) and Multidetector Computed Tomography (MDCT) for Coronary Artery Calcification**

Effective Date 12/15/2010
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Coverage Policy Number 0009

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Hyperlink to Related Coverage Policies

Cardiac Disease Risk Assessment: Emerging Laboratory Evaluations
Computed Tomography Angiography (CTA)

INSTRUCTIONS FOR USE

*Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines.*

Coverage Policy

CIGNA does not cover electron beam computed tomography (EBCT) (i.e., ultrafast), spiral computed tomography (i.e., helical), or multidetector computed tomography (MDCT) for the detection and/or quantification of coronary artery calcification because the use of these technologies for screening, diagnosis or management of coronary artery disease is considered experimental, investigational or unproven.

General Background

Note: The scope of this Coverage Policy is limited to the use of EBCT and MDCT for the evaluation of coronary artery calcification. This policy does not address cardiac CT for other indications, nor does it address calcium scoring as an adjunct to computed tomography angiography (CTA). For information on calcium scoring as an adjunct to CTA, please refer to the CIGNA Coverage Policy Computed Tomography Angiography (CTA).

Coronary artery calcification occurs in small amounts in the early lesions of atherosclerosis that appear in the second and third decades of life, but it is found more frequently in advanced lesions and in older age. The amount of calcification seen upon imaging is expressed as a score. Electron-beam computed tomography

(EBCT) and multidetector computed tomography (MDCT) are the primary “fast CT” methods proposed for coronary artery calcium (CAC) measurement at this time. Both technologies employ thin slice CT imaging, using fast scan speeds to reduce motion artifact. A fast CT study for coronary artery calcium measurement is completed within 10 to 15 minutes, requiring only a few seconds of scanning time. EBCT and MDCT have similar usefulness in terms of risk assessment. The majority of studies evaluating CAC scores to cardiovascular risk involve the use of EBCT; however, MDCT is more widely available than EBCT. In the past five to ten years, fast CT methods have been used primarily for two purposes: 1) to assist in coronary heart disease (CHD) risk assessment in asymptomatic patients, and 2) to assess the likelihood of the presence of CHD in patients who present with atypical symptoms which could be consistent with myocardial ischemia (Bonow, 2009; Greenland, et al., 2007).

Calcium Score	Presence of Plaque
0	No evidence of plaque
1–10	Minimal evidence of plaque
11–100	Mild evidence of plaque
101–400	Moderate evidence of plaque
Over 400	Extensive evidence of plaque

With very rare exception, coronary calcification is a marker of coronary atherosclerosis. The presence of coronary calcium signifies underlying coronary-artery disease, with essentially no false positive findings, although calcification is not synonymous with luminal stenosis or obstruction. The CAC score correlate closely with the volume of coronary-artery plaque measured at autopsy and is considered a surrogate for the overall coronary- plaque burden. However, postmortem studies have also shown that the total plaque volume exceeds the volume of calcified plaque by a ratio of 5 to 1. Thus, for every calcified plaque, there are many noncalcified plaques that are not detected by EBCT. It is possible for plaque erosion or rupture and myocardial infarction to occur in patients without demonstrable CAC (Bonow, 2009; Rumberger, et al., 1995).

Since the CAC score indicates the presence or absence and measures the extent of coronary atherosclerosis, it follows that multiple studies have shown that a high CAC score is a marker for an increased risk of coronary events. Therefore, a CAC score of zero is associated with a very low risk of subsequent coronary events, whereas increasing CAC scores are associated with a stepwise increase in the risk of events. What remains unclear is whether CAC scanning has a favorable effect on clinical outcomes. Also, there are concerns regarding the associated radiation exposure (Bonow, 2009).

Literature Review

Studies in the peer-reviewed scientific literature support the accuracy of EBCT/MDCT to detect CAC. Additionally, the literature demonstrates EBCT/MDCT calcium score is a valid risk assessment tool; CAC score correlates with the number and severity of conventional risk factors (e.g., cholesterol, blood pressure, triglycerides, obesity, smoking, diabetes, age, and family medical history) and may increase accuracy of risk classification when added to other risk factor tools (Polonsky, et al., 2010; Erbel, et al., 2010) but is also an independent marker for the risk of coronary events, after adjustment for these conventional risk factors. CAC provides independent and incremental prognostic information (Budoff, et al., 2009; Preis, et al. 2009; Detrano, et al., 2008; Budoff, et al., 2007; Nasir, et al., 2007; Hopkins, et al., 2006; Church, et al., 2006; LaMonte, et al., 2005; Arad, et al., 2005; Greenland, et al., 2004; Shaw, et al., 2003; Arad, et al., 2000; Schmermund, et al., 2000; O'Malley, et al., 2000; Budoff, et al., 1996).

Prospective observational studies of chest pain patients in the emergency room suggest that an absence of CAC correlates strongly with the likelihood of non-cardiac chest pain, potentially eliminating the need for additional cardiac testing. Additional long-term, well-designed trials are needed to clarify what specific population (e.g., low-risk, otherwise healthy) would benefit most from utilizing CAC to rule out chest pain of cardiac origin in the emergency room (Nabi, et al., 2010; Laudon, et al., 2010).

There is insufficient evidence in the peer-reviewed scientific literature to support the clinical utility of coronary artery calcium scoring. There is a paucity of evidence definitively demonstrating that screening with coronary calcium scoring improves clinical outcomes by reducing mortality or morbidity from CHD.

A randomized controlled trial was conducted to assess the effects of incorporating EBCT as a motivational factor into a cardiovascular screening program in the context of either intensive case management (ICM) or usual care by assessing its impact over one year on a composite measure of projected risk (O'Malley, et al., 2003). A consecutive sample of 450 asymptomatic active-duty U.S. Army personnel revealed 66 (15%) had coronary calcification. Patients were randomly assigned to one of four intervention arms: EBCT results provided in the setting of either ICM (n=111) or usual care (n=119) or EBCT results withheld in the setting of either ICM (n=124) or usual care (n=96). The primary outcome measure was change in a composite measure of risk, the 10-year Framingham Risk Score (FRS). Improvement or stabilization of cardiovascular risk was noted in 157 patients (40.2%). In multivariable analyses predicting change in FRS, after controlling for knowledge of coronary calcification, motivation for change, and multiple psychological variables, only the number of risk factors and receipt of ICM were associated with improved or stabilized projected risk. This study indicated that using coronary calcification screening to motivate patients to make evidence-based changes in risk factors was not associated with improvement in modifiable cardiovascular risk at one year.

Technology Assessments

The Institute for Clinical Systems Improvement (ICSI) Health Care Guideline on Preventive Services for Adults (October 2009) addresses coronary heart disease routine testing, assigning Level IV evidence rating (Preventive services that are not supported by evidence and not recommended. Level IV services are those with low predictive value and/or uncertain beneficial action for true positives). The ICSI recommends against routine screening with resting electrocardiogram (ECG), exercise treadmill test (ETT) or electron-beam computerized tomography (EBCT) scanning for coronary artery calcium in adults at low risk for CHD events. The use of ECG, ETT or EBCT for screening of low-risk asymptomatic adults for coronary artery disease can lead to false-positive tests, producing expense and physical/psychological damage without evidence of benefit. While these tests may detect a small number of individuals at increased risk of coronary heart disease or with coronary artery stenosis, there is not evidence that this detection for low risk adults ultimately improves outcomes (Fowler-Brown, et al., 2004). The use of these tests for screening in adults at increased risk for coronary heart disease events continues to be reviewed and currently shows insufficient evidence to recommend for or against screening in this population and is out of the scope of this guideline (September, 2010).

The National Health Service (NHS), United Kingdom, published a Health Technology Assessment evaluating computed tomography screening for CAD. This systematic review concluded that:

- "CT examination of the coronary arteries can detect calcification indicative of arterial disease in asymptomatic people, many of whom would be at low risk when assessed by traditional risk factors. The higher the CAC score, the higher the risk. Treatment with statins can reduce that risk.
- However, CT screening would miss many of the most dangerous patches of arterial disease, because they are not yet calcified, and so there would be false-negative results: normal CT followed by a heart attack. There would also be false-positive results in that many calcified arteries will have normal blood flow and will not be affected by clinically apparent thrombosis: abnormal CT not followed by a heart attack.
- For CT screening to be cost-effective, it has to add value over risk factor scoring, by producing sufficient extra information to change treatment and hence cardiac outcomes, at an affordable cost per quality-adjusted life-year. There was insufficient evidence to support this" (Waugh, et al., 2006).

California Technology Assessment Forum (CTAF) Assessment on Utility of Coronary Artery Calcium Measurements in Cardiovascular Disease (February 2005) recommended that the use of EBCT to measure coronary artery calcification (CAC):

- As a screening test to identify asymptomatic patients at high risk for future coronary heart disease events does not meet technology assessment criteria 3, 4, or 5 for safety, effectiveness, and improvement in health outcomes
- As a diagnostic test in patients with symptoms suggestive of CAD does not meet technology assessment criteria 3, 4, or 5 for safety, effectiveness, and improvement in health outcomes
- To assess response to therapy for coronary heart disease does not meet technology assessment criteria 2, 3, 4, or 5 for safety, effectiveness, and improvement in health outcomes (February 2005).

Professional Societies/Organizations

U.S. Preventive Services Task Force (USPSTF)

The USPSTF Recommendation Statement on Using Nontraditional Risk Factors In Coronary Heart Disease Risk Assessment (October 2009) concludes that the current evidence is insufficient to assess the balance of benefits and harms of using the nontraditional risk factors discussed in this statement to screen asymptomatic men and women with no history of CHD to prevent CHD events. (Grade: I [Insufficient] Statement, current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.)

The nontraditional risk factors included in this recommendation are high-sensitivity C-reactive protein (hs-CRP), ankle–brachial index (ABI), leukocyte count, fasting blood glucose level, periodontal disease, carotid intima–media thickness (carotid IMT), coronary artery calcification (CAC) score on electron-beam computed tomography (EBCT), homocysteine level, and lipoprotein(a) level. (October 2009).

American College of Cardiology Foundation (ACCF)/American Heart Association (AHA)
The ACCF/AHA 2007 clinical expert consensus document on coronary artery calcium scoring by computed tomography in global cardiovascular risk assessment and in evaluation of patients with chest pain (Greenland, et al., 2007) states that:

- CAC scoring has an increasingly high level of quality evidence on its role in risk stratification of asymptomatic patients. Recent evidence is supportive that measurement of CAC is predictive of CHD death or MI at three to five years. Current evidence also suggests that the use of CAC is independently predictive of outcome over and above traditional cardiac risk factors. Published reports have largely been derived from patient cohorts where referral bias is operational resulting in an overestimation of CHD death or MI risk estimates. Upcoming data from the MESA study may be helpful to devise population screening strategies.
- The consensus of the Committee was that the body of evidence is supportive of recommendations from the U.S. Preventive Services Task Force (USPSTF) that unselected screening is of limited clinical value in asymptomatic patients who are at low risk for CHD events, typically estimated using a low FRS less than 1.0% per year.
- For the symptomatic patient, exclusion of measurable coronary calcium may be an effective filter before undertaking invasive diagnostic procedures or hospital admission.
- Although progression of CAC can be detected using fast CT methods, its determinants are largely unknown, and the relationship to clinical outcomes is still unclear. (Greenland, et al., 2007).

ACCF/American College of Radiology (ACR)
In the ACCF/ACR Appropriateness Criteria for Cardiac Computed Tomography and Cardiac Magnetic Resonance Imaging (Hendel, et al., 2006), a total of four CT indications addressing calcium scoring were rated,* none appropriate, two uncertain and two inappropriate:

For Risk Assessment: General Population (asymptomatic) Calcium Scoring is:
- Inappropriate, if low coronary heart disease (CHD) risk (Framingham)
- Uncertain, if moderate CHD risk (Framingham)
- Uncertain, if high CHD risk (Framingham)

For Risk Assessment with Prior Test Results, patient is asymptomatic, Calcium Scoring is:
- Inappropriate, if prior calcium score within previous five years

*Ratings:
- Appropriate test for specific indication (test is generally acceptable and is a reasonable approach for the indication).
- Uncertain for specific indication (test may be generally acceptable and may be a reasonable approach for the indication). Uncertainty also implies that more research and/or patient information is needed to classify the indication definitively.
- Inappropriate test for that indication (test is not generally acceptable and is not a reasonable approach for the indication) (Hendel, et al., 2006).

American Heart Association (AHA)
The AHA published a scientific statement on assessment of CAD by cardiac computed tomography in October 2006 (Budoff, et al., 2006). There was no Class* I or IIa recommendations regarding cardiac CT:

- Low-risk (<10% ten-year risk) and high-risk (>20% ten-year risk) patients do not benefit from CAC measurement—Class III
- It may be reasonable to measure atherosclerosis burden using EBCT or MDCT in clinically selected intermediate-CAD risk patients (e.g., those with a 10% to 20% Framingham ten-year risk estimate) to refine clinical risk prediction and to select patients for more aggressive target values for lipid-lowering therapies—Class IIb
- Coronary calcium assessment may be reasonable for the assessment of symptomatic patients, especially in the setting of equivocal treadmill or functional testing—Class IIb
- Patients with chest pain with equivocal or normal ECGs and negative cardiac enzyme studies may be considered for CAC assessment—Class IIb
- Coronary artery calcified plaque measurement may be considered in the symptomatic patient to determine the cause of cardiomyopathy—Class IIb
- Imaging of patients to follow-up stent placement cannot be recommended—Class III
- Serial imaging for assessment of progression of coronary calcification is not indicated at this time— Class III
- There are no data supporting the use of hybrid scanning to assess cardiovascular risk or presence of obstructive disease—Class III

*American College of Cardiology/American Heart Association (ACC/AHA) Definitions of Classification used:
Class I: Conditions for which there is evidence for and/or general agreement that the procedure or treatment is beneficial, useful, and effective.
Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/ efficacy of a procedure or treatment.
Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.
Class IIb: Usefulness/efficacy is less well established by evidence/opinion.
Class III: Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful.

American College of Radiology (ACR)
The ACR (October, 2006) states that "unenhanced ECG-gated cardiac CT may be indicated for detecting and quantifying CAC ("calcium scoring"). While the role of CAC scoring is currently being refined, data support its use for risk stratification and therapeutic decision- making in select patients with intermediate risk for a significant ischemic cardiac event. An additional indication is the localization of myocardial and pericardial calcium."

Summary
There are numerous longitudinal observational studies validating that coronary artery calcium (CAC) is a prognostic parameter with significant predictive power regarding the development of future cardiac events. However, there is insufficient evidence in the peer-reviewed scientific literature demonstrating that screening with coronary calcium scoring improves clinical outcomes by reducing mortality or morbidity from coronary heart disease. Additionally, studies do not address benefit versus harm (e.g., associated radiation exposure). There remains a lack of consensus regarding what actions, if any, should be taken based upon the score.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not Covered:

CPT®* Codes	Description
75571	Computed tomography, heart, without contrast material, with quantitative evaluation of coronary calcium

HCPCS Codes	Description

S8092	Electron beam computed tomography (also known as ultrafast CT, cine CT)

ICD-9-CM Diagnosis Codes	Description
414.00-414.07	Coronary atherosclerosis
414.2	Chronic total occlusion of coronary artery
414.3	Coronary atherosclerosis due to lipid rich plaque
440.9	Generalized and unspecified atherosclerosis
V81.0	Special screening for cardiovascular, respiratory, and genitourinary diseases; Ischemic heart disease

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	12/15/2007	0009	Electron Beam Computed Tomography (EBCT) and Multidetector Computed Tomography (MDCT) for Coronary Artery Calcification
Great-West Healthcare	11/27/07	99.308.05	Computed Tomography (CT), Without Contrast, for Coronary Artery Disease