
Medical Policy



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***Current Policy Effective Date: 9/1/22**
(See policy history boxes for previous effective dates)

Title: Computed Tomography to Detect Coronary Artery Calcification

Description/Background

CORONARY ARTERY CALCIUM

Coronary artery calcium (CAC) is associated with coronary artery disease (CAD). The development of fast computed tomography (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 of CAD in patients with subclinical disease, with the goal of instituting appropriate risk-reducing therapy (eg, statin treatment, lifestyle modifications) to improve outcomes. Also, CAC has been evaluated in patients with symptoms potentially consistent with CAD, but in whom a diagnosis is unclear.

Detection

Electron-beam computed tomography (EBCT; also known as ultrafast CT) and spiral CT (or helical CT) may be used as an alternative to conventional CT scanning due to faster throughput. In both methods, the speed of image acquisition gives them unique value for imaging a moving heart. 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 CAC, 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.

Electron-beam computed tomography and multidetector CT were initially the primary fast CT methods for measurement of CAC. A fast CT study for CAC measurement takes 10 to 15 minutes and requires only a few seconds of scanning time. More recently, computed

tomography angiography has been used to assess coronary calcium. Because of the basic similarity between EBCT and computed tomography angiography in measuring coronary calcium, it is expected that computed tomography angiography provides information on coronary calcium that is similar to EBCT.

Computed tomography scan-derived coronary calcium measures have been used to evaluate coronary atherosclerosis. Coronary calcium is present in coronary atherosclerosis, but 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, coronary calcium 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, coronary calcium scores might help determine whether there is an 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 determine a specific diagnosis. Most clinical studies have examined coronary calcium for its potential use in estimating the risk of future coronary heart disease events.

Risk Assessment Tool

The ASCVD (atherosclerotic cardiovascular disease) pooled cohort risk score is based on national guidelines developed by the American College of Cardiology. It is a calculation of an individual's 10-year risk of having a cardiovascular problem, such as a heart attack or stroke. This risk estimate considers age, sex, race, cholesterol levels, blood pressure, medication use, diabetes status, and smoking status. Risk assessment is a critical step in the current approach to primary prevention of atherosclerotic cardiovascular disease (myocardial infarction, heart failure, atherosclerosis and stroke). The pooled cohort equation has been widely validated and is broadly useful for the general US clinical population. But the risk assessment tool may systematically underestimate risk in certain patient groups, and overestimate risk in others. Therefore when uncertainty remains, as for patients at borderline (ASCVD risk score of 5 to 7.5) or intermediate risk (ASCVD risk score of 7.6 to 19.9), or if the patient is undecided after a patient–clinician discussion with consideration of risk enhancing factors (eg, family history), additional testing with measurement of coronary artery calcium can be useful to reclassify risk estimates and improve selection of patients for use or avoidance of statin therapy.⁶

Nomenclature

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 (low risk) to 400 (high risk). 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.

Regulatory Status:

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

Medical Policy Statement

Computed tomography for the detection of coronary artery calcification is considered established when criteria are met.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

Benefits must be verified. Employer groups may decline coverage of this test.

Inclusions:

Coronary artery calcium (CAC) testing is considered established to assist with decisions regarding management of hypercholesterolemia when ALL of the following apply:

- No known atheromatous vascular disease
- Not diabetic
- Age ≥ 40 years and ≤ 75 years
- Low-density lipoprotein (LDL) cholesterol ≥ 70 mg/dL and ≤ 190 mg/dL
- 10-year risk (using atherosclerotic cardiovascular disease [ASCVD] Pooled Cohort Equations) $\geq 5\%$ and $\leq 20\%$

Exclusions:

ANY of the following:

- Family history of premature atherosclerotic cardiovascular disease
- Persistently elevated low-density lipoprotein (≥ 160 mg/dL)
- Persistently elevated triglyceride (> 175 mg/dL)
- Metabolic syndrome
- Chronic kidney disease (eGFR 15-59 mL/min/1.73 m²)
- Chronic inflammatory condition
- History of menopause before age 40 years
- History of preeclampsia
- High risk race/ethnicity (eg, South Asian ancestry)
- Markers associated with increased risk of atherosclerotic cardiovascular disease (if measured):
 - Elevated high-sensitivity C-reactive protein (≥ 2.0 mg/L)
 - Elevated lipoprotein(a) (> 50 mg/dL)
 - Apolipoprotein B > 130 mg/dL
 - Ankle-brachial index less than 0.9

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

75571 S8092

Other codes (investigational, not medically necessary, etc.):

NA

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

McClelland et al (2015) sought to derive and validate a novel risk score to estimate 10-year coronary heart disease risk using coronary artery calcium and traditional risk factors.¹ Algorithm development was conducted in the MESA (Multi-Ethnic Study of Atherosclerosis), a prospective community-based cohort study of 6,814 participants age 45 years to 84 years, who were free of clinical heart disease at baseline and were followed for 10 years. The MESA study is sex balanced and included 39% non-Hispanic whites, 12% Chinese Americans, 28% African Americans, and 22% Hispanic Americans. External validation was conducted in the Heinz Nixdorf Recall Study (HNR) and the Dallas Heart Study (DHS). The authors found that inclusion of coronary artery calcium, in the MESA risk score offered significant improvements in risk prediction (C-statistic 0.80 vs. 0.75; p<0.0001). External validation in both the HNR and DHS studies provided evidence of very good discrimination and calibration. The difference in estimated 10-year risk between events and nonevents was approximately 8% to 9%, indicating excellent discrimination. Mean calibration, or calibration-in-the-large, was excellent for both studies, with average predicted 10-year risk within one-half of a percent of the observed event rate. The authors concluded that an accurate estimate of 10-year coronary heart disease risk can be obtained using traditional risk factors and coronary artery calcium.

Supplemental Information

**ACCF/SCCT/ACR/AHA/ASE/ASNC/NASCI/SCAI/SCMR 2010²
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 for Cardiovascular Imaging, the Society for Cardiovascular Angiography and Interventions, and the Society for Cardiovascular Magnetic Resonance

Noncontrast CT calcium scoring was judged as appropriate for intermediate CHD risk patients, and for the specific subset of low-risk patients in whom a family history of premature CHD was present. Intermediate risk was defined as a 10-year risk of between 10% and 20%, although individual patient exceptions to a broadened intermediate risk range of 6% to 20% were recognized for certain patient subsets with generally low absolute risk but high relative risk (younger men and women).

ACCF/AHA guideline for assessment of cardiovascular risk in asymptomatic adults: executive summary 2010³

A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines

Recommendations for Calcium Scoring Methods

Class IIa

1. Measurement of CAC is reasonable for cardiovascular risk assessment in asymptomatic adults at intermediate risk (10% to 20% 10-year risk). (Level of Evidence: B)

Class IIb

1. Measurement of CAC may be reasonable for cardiovascular risk assessment in persons at low to intermediate risk (6% to 10% 10-year risk). (Level of Evidence: B)

Class III: No Benefit

1. Persons at low risk (<6% 10-year risk) should not undergo CAC measurement for cardiovascular risk assessment. (Level of Evidence: B)

Key: Class I: Procedure/treatment SHOULD be performed/administered
Class IIa: IT IS REASONABLE to perform procedure/administer treatment
Class IIb: Procedure/treatment MAY BE CONSIDERED
Class III: No benefit

AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA 2018⁴

Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines

“Top 10 Take-Home Messages to Reduce Risk of Atherosclerotic Cardiovascular Disease Through Cholesterol Management”

In discussion of the scope of the guideline:

“...when risk status is uncertain, a coronary artery calcium (CAC) score is an option to facilitate decision-making in adults ≥ 40 years of age”.

Guideline 9:

In adults 40 to 75 years of age without diabetes mellitus and with LDL-C levels ≥ 70 mg/dL to 189 mg/dL (≥ 1.8 -4.9 mmol/L), at a 10-year ASCVD risk of $\geq 7.5\%$ to 19.9%, if a decision about statin therapy is uncertain, consider measuring coronary artery calcium (CAC). If CAC is zero, treatment with statin therapy may be withheld or delayed, except in cigarette smokers, those with diabetes mellitus, and those with a strong family history of premature ASCVD. A CAC score of 1 to 99 favors statin therapy, especially in those ≥ 55 years of age. For any patient, if the CAC score is ≥ 100 Agatston units or ≥ 75 th percentile, statin therapy is indicated unless otherwise deferred by the outcome of clinician–patient risk discussion.

ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines 2019⁵

The guideline states:

For individuals with intermediate predicted risk ($\geq 7.5\%$ to $< 20\%$) by the PCE or for select adults with borderline (5% to $< 7.5\%$) predicted risk, coronary artery calcium measurement can be a useful tool in refining risk assessment for preventive interventions (eg, statin therapy). In these groups, coronary artery calcium measurement can reclassify risk upward (particularly if coronary artery calcium score is ≥ 100 Agatston units (AU) or ≥ 75 th age/sex/race percentile) or downward (if coronary artery calcium is zero) in a significant proportion of individuals. The extent of reclassification is sufficient to provide confidence that borderline- or intermediate-risk patients with elevated coronary artery calcium will have event rates that clearly exceed benefit thresholds (ie, $\geq 7.5\%$ in 10 years) and those with coronary artery calcium scores of zero will have event rates $< 7.5\%$, which can help guide shared decision-making about statins or potentially even aspirin. In observational data, the presence and severity of coronary artery calcium have been shown to be associated with the likelihood of benefit from statin therapy for ASCVD risk reduction. Coronary artery calcium scoring has superior discrimination and risk reclassification as compared with other subclinical imaging markers or biomarkers.

American Heart Association and American College of Cardiology Special Report 2019⁶

Use of Risk Assessment Tools to Guide Decision-Making in the Primary Prevention of Atherosclerotic Cardiovascular Disease

The report states:

“In patients 40 to 75 years of age and at intermediate risk, substantial data indicate that use of coronary artery calcium (CAC) measurement can be effective in reclassifying risk meaningfully in a large proportion of individuals. In this intermediate-risk range, those who also have CAC measurement of ≥ 100 AU (or 75th percentile for age/sex/race/ethnicity) have event rates in the range where the benefit of statin therapy would clearly exceed any potential for harms. Additionally, such data can inform a patient and clinician regarding higher likelihood of benefit from drug therapy. Conversely, those with intermediate predicted risk and CAC score of 0 AU appear to have lower 10-year event rates ($< 7.5\%$), suggesting that drug therapy could be of limited value.

Government Regulations

National:

There is no national coverage determination addressing this procedure.

Local:

Wisconsin Physicians Service Insurance Corporation (WPS)

Local Coverage Determination (LCD): Coronary Computed Tomography Angiography (CCTA) (L35121)

Original Effective Date 10/01/2015

Revision Effective Date 10/28/2021

Limitations:

This LCD does not address electron beam tomography (EBT) technology or Ultrafast CT for coronary artery examination. There is no extension of coverage of EBT based on this policy.

Quantitative calcium scoring is not a covered service and will be denied as not medically necessary. Calcium scoring reported in isolation is considered a screening service. When performed in association with CT angiography, there is neither separate nor additional included reimbursement for the calcium scoring.

Wisconsin Physicians Service Insurance Corporation (WPS)
Local Coverage Article: Billing and Coding: Coronary Computed Tomography Angiography (CCTA) (A57552)
Original Effective Date 11/28/2019
Revision Effective Date 01/01/2022

75571 is listed in the Group 2 Non-covered codes table.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Contrast-Enhanced Computed Tomography Angiography (CTA, CCTA, MDCT, MSCT) of the Heart and/or Coronary Arteries

References

1. McClelland RL, Jorgensen NW, Budoff M, et al. 10-Year coronary heart disease risk prediction using coronary artery calcium and traditional risk factors: derivation in the MESA (Multi-Ethnic Study of Atherosclerosis) with validation in the HNR (Heinz Nixdorf Recall) Study and the DHS (Dallas Heart Study) J Am Coll Cardiol. 2015;66:1643–53. PMID 26449133
2. Taylor AJ, Cerqueira M, Hodgson JM, et al. ACCF/SCCT/ACR/AHA/ASE/ASNC/SCAI/SCMR 2010 appropriate use criteria for cardiac computed tomography. J Am Coll Cardiol. 2010;56(22):1864-1894. <https://www.ahajournals.org/doi/10.1161/cir.0b013e3181fcae66> Accessed 4/29/22.
3. Greenland P, Alpert JS, Beller GA, et al. 2010 ACCF/AHA guideline for assessment of cardiovascular risk in asymptomatic adults: executive summary. J Am Coll Cardiol. 2010;56(25):2182-2199. <https://www.ahajournals.org/doi/epub/10.1161/CIR.0b013e3182051bab> Accessed 4/29/22.
4. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APHA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. June 18 2019;139(25):e1082-e1143 PMID

30586774 <https://www.ahajournals.org/doi/10.1161/cir.0000000000000625> Accessed 4/29/22.

5. Arnett DK, Blumenthal RS, Albert MA, et al. 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation*. Sep 10 2019; 140(11): e596-e646. PMID 30879355
<https://www.ahajournals.org/doi/10.1161/CIR.0000000000000678#:~:text=Adults%20should%20engage%20in%20at,achieving%20exercise%20recommendations%2C%20are%20crucial>. Accessed 4/29/22.
6. Lloyd-Jones DM, Braun LT, Ndumele CE, et al. Use of Risk Assessment Tools to Guide Decision-Making in the Primary Prevention of Atherosclerotic Cardiovascular Disease: A Special Report From the American Heart Association and American College of Cardiology. *Circulation*. Jun 18 2019;139(25):e1162-e1177 PMID 30586766
<https://www.ahajournals.org/doi/full/10.1161/CIR.0000000000000638> Accessed 4/29/22.
7. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination: Coronary Computed Tomography Angiography (CCTA). Original effective date 10/01/2015. Revision effective date 10/28/2021. <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=35121&ver=29&bc=0> Accessed 4/29/22.
8. Wisconsin Physicians Service Insurance Corporation. Local Coverage Article Billing and Coding: Coronary Computed Tomography Angiography (CCTA). Original effective date 11/28/2019. Revision effective date 01/01/2022. <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=57552&ver=8&bc=0> Accessed 4/29/22.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 4/29/22, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
6/3/02	6/3/02	7/2/02	Joint policy established
2/16/04	2/16/04	3/1/04	Routine maintenance
6/15/05	6/15/05	5/20/05	Routine maintenance
1/10/06	1/10/06	3/10/06	Routine maintenance
3/1/08	12/11/07	11/18/07	Routine maintenance
9/1/10	6/15/10	6/29/10	Routine maintenance
9/1/11	6/21/11	6/21/11	Routine maintenance
11/1/11	8/16/11	8/16/11	Routine maintenance; title changed from Electron Beam Computed Tomography (EBCT) for Coronary Artery Disease to Computed Tomography to Detect Coronary Artery Calcification. Added CPT code 75571 to policy
5/1/13	2/19/13	3/4/13	Routine maintenance
3/1/15	12/12/14	12/29/14	Routine maintenance
7/1/16	4/19/16	4/19/16	Routine maintenance
1/1/17	10/11/16	10/11/16	Routine maintenance
1/1/18	10/19/17	10/19/17	Routine maintenance
1/1/19	10/16/18	10/16/18	Routine maintenance
1/1/20	10/15/19		Routine maintenance
1/1/21	10/20/20		Routine maintenance Ref added: 8,11,12,13,29
5/1/21	2/16/21		Routine maintenance
3/1/22	12/14/21		Routine maintenance Ref added: 4, 5
9/1/22	6/21/22		Routine maintenance Position change to covered, with criteria. Ref 1-5 added. Risk score section added to Background.

Next Review Date: 2nd Qtr, 2023

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: COMPUTED TOMOGRAPHY TO DETECT CORONARY ARTERY CALCIFICATION

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.