UM-CDG-060 AI Enabled CT Based Quantitative Coronary Topography Coronary Plaque Analysis	Approved By: Director, Health Services	Effective Date: 10/20/2025

This Policy applies to all SECUR affiliates, associates, and subsidiaries.

Approved by Courtney Gonzales, Director of Health Services on behalf of the Utilization Management Committee.

PURPOSE

This coverage determination guideline serves to address artificial intelligence (AI) enabled computed tomography (CT) based quantitative coronary topography (AI-QCT) and coronary plaque analysis (AI-CPA), imaging obtained through coronary CT scans to calculate coronary artery dimensions and degree of stenosis per vessel and coronary plaque composition and burden.

For SECUR Health Plan members, National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) will be applied to requests when applicable. SECUR Health Plan Coverage Determination Guidelines (CDG) will be utilized in the absence of an appropriate NCD and/or LCD.

DEFINITIONS

None

RELATED POLICY(IES)

UM-CDG-008 Computed Tomographic Angiography of the Chest, Heart, and Coronary Arteries

POLICY

SECUR Health Plan will consider AI-QCT/AI-CPA using coronary computed tomography angiography (CCTA) as medically necessary as a diagnostic study when:

1. Member has acute or stable chest pain with no known coronary artery disease (CAD) and is eligible for CCTA, and
2. CCTA classifies member as intermediate risk or CAD-RADS 1, CAD-RADS 2, or CAD-RADS 3 category on CCTA, and
3. Cardiac evaluation is negative or inconclusive for acute coronary syndrome (ACS).

SECUR Health Plan will follow the guidance in UM-CDG-008 for criteria for CCTA. AI-QCT/AI-CPA should not be performed until after the base study (CCTA) has been completed and interpreted. Software to perform AI-QCT/AI-CPA must be US Food and Drug Administration (FDA) cleared or approved.

SECUR Health Plan does not consider AI-QCT/AI-CPA as medically necessary in the following:

1. Screening
2. When there is a contraindication to CCTA
3. In conjunction with invasive coronary catheterization
4. In the presence of normal CCTA results
5. In the presence of high grade stenosis (greater than 70%)

6. Within thirty (30) days of a myocardial infarction (MI)
7. In the presence of unstable coronary symptoms
8. For disease surveillance

Coronary Artery Disease Reporting and Data System (CAD-RADS)

Category	Degree of maximal coronary stenosis	Interpretation
CAD-RADS 0	0%	Absence of CAD
CAD-RADS 1	1-24%	Minimal non-obstructive CAD
CAD-RADS 2	25-49%	Mild non-obstructive CAD
CAD-RADS 3	50-69%	Moderate stenosis
CAD-RADS 4	70-99% or left main ≥50% or 3-vessel obstructive (≥70%) disease	Severe stenosis
CAD-RADS 5	100%	Total coronary artery occlusion or sub-total occlusion
CAD-RADS N	Non-diagnostic study	Obstructive CAD cannot be excluded

References:

1. Gulati M, Levy PD, Mukherjee D, et al. 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Cardiovasc Comput Tomogr*. 2021;16(1):54-122.
2. Cury RC, Leipsic J, Abbara S, et al. CAD-RADS™ 2.0–2022 coronary artery disease-reporting and data system: an expert consensus document of the society of cardiovascular computed tomography (SCCT), the American college of cardiology (ACC), the American college of radiology (ACR), and the North America society of cardiovascular imaging (NASCI). *Cardiovascular Imaging*. 2022;15(11):1974-2001.
3. Correction to: 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2021;144(22):e455.
4. Choi AD, Marques H, Kumar V, et al. CT Evaluation by Artificial Intelligence for Atherosclerosis, Stenosis and Vascular Morphology (CLARIFY): A Multi-center, international study. *J Cardiovasc Comput Tomogr*. 2021;15(6):470-476.
5. Budoff MJ, Lakshmanan S, Toth PP, et al. Cardiac CT angiography in current practice: An American society for preventive cardiology clinical practice statement(). *Am J Prev Cardiol*. 2022;9:100318.
6. Nieman K, García-García HM, Hideo-Kajita A, et al. Standards for quantitative assessments by coronary computed tomography angiography (CCTA): An expert consensus document of the society of cardiovascular computed tomography (SCCT). *Journal of Cardiovascular Computed Tomography*. 2024.
7. Nerlekar N, Ha FJ, Cheshire C, et al. Computed Tomographic Coronary Angiography-Derived Plaque Characteristics Predict Major Adverse Cardiovascular Events: A Systematic Review and Meta-Analysis. *Circ Cardiovasc Imaging*. 2018;11(1):e006973.
8. Williams MC, Kwiecinski J, Doris M, et al. Low-Attenuation Noncalcified Plaque on Coronary Computed Tomography Angiography Predicts Myocardial Infarction: Results From the Multicenter SCOT-HEART Trial (Scottish Computed Tomography of the HEART). *Circulation*. 2020;141(18):1452-1462.
9. FDA. 510(k) Premarket Notification https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K202280 . Published 2020. Updated 10/02/2020. Accessed 08/13/2024.
10. Budoff MJ, Bhatt DL, Kinninger A, et al. Effect of icosapent ethyl on progression of coronary atherosclerosis in patients with elevated triglycerides on statin therapy: final results of the EVAPORATE

trial. *Eur Heart J*. 2020;41(40):3925-3932.
11. Nielsen LH, Ortner N, Nørgaard BL, Achenbach S, Leipsic J, Abdulla J. The diagnostic accuracy and outcomes after coronary computed tomography angiography vs. conventional functional testing in patients with stable angina pectoris: a systematic review and meta-analysis. *European Heart Journal - Cardiovascular Imaging*. 2014;15(9):961-971.
12. Narula J, Chandrashekhar Y, Ahmadi A, et al. SCCT 2021 expert consensus document on coronary computed tomographic angiography: a report of the Society of Cardiovascular Computed Tomography. *Journal of cardiovascular computed tomography*. 2021;15(3):192-217.
13. Nakanishi R, Motoyama S, Leipsic J, Budoff MJ. How accurate is atherosclerosis imaging by coronary computed tomography angiography? *Journal of cardiovascular computed tomography*. 2019;13(5):254-260.
14. ECRI. Cleerly Coronary Data Visualization Platform (Cleerly Health) for Aiding Diagnosis of Coronary Artery Disease. https://www.ecri.org/components/ProductBriefs/Pages/210682.aspx . Published 2021. Updated 7/1/2021. Accessed October 28, 2022.
15. Newby DE, Adamson PD, Berry C, et al. Coronary CT Angiography and 5-Year Risk of Myocardial Infarction. *N Engl J Med*. 2018;379(10):924-933.
16. Williams MC KJ, Doris M, et al. . CT coronary angiography in patients with suspected angina due to coronary heart disease (SCOT-HEART): an open-label, parallel-group, multicentre trial. *The Lancet*. 2015;385(9985):2383-2391.
17. Williams MC, Moss AJ, Dweck M, et al. Coronary artery plaque characteristics associated with adverse outcomes in the SCOT-HEART study. *Journal of the American College of Cardiology*. 2019;73(3):291-301.
18. Singh T, Bing R, Dweck MR, et al. Exercise electrocardiography and computed tomography coronary angiography for patients with suspected stable angina pectoris: a post hoc analysis of the randomized SCOT-HEART trial. *JAMA cardiology*. 2020;5(8):920-928.
19. Bienstock S, Lin F, Blankstein R, et al. Advances in coronary computed tomographic angiographic imaging of atherosclerosis for risk stratification and preventive care. *Cardiovascular Imaging*. 2023;16(8):1099-1115.
20. Lin A, Manral N, McElhinney P, et al. Deep learning-enabled coronary CT angiography for plaque and stenosis quantification and cardiac risk prediction: an international multicentre study. *Lancet Digit Health*. 2022;4(4):e256-e265.
21. Douglas PS, Hoffmann U, Patel MR, et al. Outcomes of Anatomical versus Functional Testing for Coronary Artery Disease. *New England Journal of Medicine*. 2015;372(14):1291-1300.
22. Hoffmann U, Ferencik M, Udelson JE, et al. Prognostic Value of Noninvasive Cardiovascular Testing in Patients With Stable Chest Pain: Insights From the PROMISE Trial (Prospective Multicenter Imaging Study for Evaluation of Chest Pain). *Circulation*. 2017;135(24):2320-2332.
23. Ferencik M, Mayrhofer T, Bittner D, et al. Use of High-Risk Coronary Atherosclerotic Plaque Detection for Risk Stratification of Patients With Stable Chest Pain: A Secondary Analysis of the PROMISE Randomized Clinical Trial. *JAMA cardiol* 2018;3(2):144-152.
24. Bhindi R, Guan M, Zhao Y, Humphries KH, Mancini GJ. Coronary atheroma regression and adverse cardiac events: a systematic review and meta-regression analysis. *Atherosclerosis*. 2019;284:194-201.
25. Lee SE, Chang HJ, Sung JM, et al. Effects of Statins on Coronary Atherosclerotic Plaques: The PARADIGM Study. *JACC Cardiovasc Imaging*. 2018;11(10):1475-1484.
26. van Rosendael AR, Lin FY, van den Hoogen IJ, et al. Progression of whole-heart Atherosclerosis by coronary CT and major adverse cardiovascular events. *J Cardiovasc Comput Tomogr*. 2021;15(4):322-330.
27. van Rosendael AR, van den Hoogen IJ, Gianni U, et al. Association of Statin Treatment With Progression of Coronary Atherosclerotic Plaque Composition. *JAMA Cardiol*. 2021;6(11):1257-1266.

28. Perez de Isla L, Diaz-Diaz JL, Romero MJ, et al. Alirocumab and Coronary Atherosclerosis in Asymptomatic Patients with Familial Hypercholesterolemia: The ARCHITECT Study. *Circulation*. 2023;147(19):1436-1443.
29. Hirai K, Imamura S, Hirai A, Ookawara S, Morishita Y. Effect of Evolocumab on Vulnerable Coronary Plaques: A Serial Coronary Computed Tomography Angiography Study. *J Clin Med*. 2020;9(10).
30. Nicholls SJ, Puri R, Anderson T, et al. Effect of Evolocumab on Progression of Coronary Disease in Statin-Treated Patients: The GLAGOV Randomized Clinical Trial. *Jama*. 2016;316(22):2373-2384.
31. Vaidya K, Arnott C, Martínez GJ, et al. Colchicine Therapy and Plaque Stabilization in Patients With Acute Coronary Syndrome: A CT Coronary Angiography Study. *JACC Cardiovasc Imaging*. 2018;11(2 Pt 2):305-316.
32. Reynolds HR, Shaw LJ, Min JK, et al. Outcomes in the ISCHEMIA Trial Based on Coronary Artery Disease and Ischemia Severity. *Circulation*. 2021;144(13):1024-1038.
33. Ferencik M, Mayrhofer T, Puchner SB, et al. Computed tomography-based high-risk coronary plaque score to predict acute coronary syndrome among patients with acute chest pain—Results from the ROMICAT II trial. *J Cardiovasc Comput Tomogr*. 2015;9(6):538-545.
34. Puchner SB, Liu T, Mayrhofer T, et al. High-risk plaque detected on coronary CT angiography predicts acute coronary syndromes independent of significant stenosis in acute chest pain: results from the ROMICAT-II trial. *J Am Coll Cardiol*. 2014;64(7):684-692.
35. Lu MT, Meyersohn NM, Mayrhofer T, et al. Central Core Laboratory versus Site Interpretation of Coronary CT Angiography: Agreement and Association with Cardiovascular Events in the PROMISE Trial. *Radiology*. 2018;287(1):87-95.
36. Stuijfzand WJ, Van Rosendael AR, Lin FY, et al. Stress myocardial perfusion imaging vs coronary computed tomographic angiography for diagnosis of invasive vessel-specific coronary physiology: predictive modeling results from the computed tomographic evaluation of atherosclerotic determinants of myocardial ischemia (CREDENCE) trial. *JAMA cardiology*. 2020;5(12):1338-1348.
37. Greenwood JP, Maredia N, Younger JF, et al. Cardiovascular magnetic resonance and single-photon emission computed tomography for diagnosis of coronary heart disease (CE-MARC): a prospective trial. *Lancet*. 2012;379(9814):453-460.
38. Maron DJ, Hochman JS, Reynolds HR, et al. Initial Invasive or Conservative Strategy for Stable Coronary Disease. *N Engl J Med*. 2020;382(15):1395-1407.
39. Lipkin I, Telluri A, Kim Y, et al. Coronary CTA With AI-QCT Interpretation: Comparison With Myocardial Perfusion Imaging for Detection of Obstructive Stenosis Using Invasive Angiography as Reference Standard. *AJR Am J Roentgenol*. 2022;219(3):407-419.
40. Griffin WF, Choi AD, Riess JS, et al. AI Evaluation of Stenosis on Coronary CTA, Comparison With Quantitative Coronary Angiography and Fractional Flow Reserve: A CREDENCE Trial Substudy. *JACC Cardiovasc Imaging*. 2023;16(2):193-205.
41. Yang S, Hoshino M, Koo BK, et al. Relationship of Plaque Features at Coronary CT to Coronary Hemodynamics and Cardiovascular Events. *Radiology*. 2022;305(3):578-587.
42. Dundas J, Leipsic J, Fairbairn T, et al. Interaction of AI-Enabled Quantitative Coronary Plaque Volumes on Coronary CT Angiography, FFRCT, and Clinical Outcomes: A Retrospective Analysis of the ADVANCE Registry. *Circulation: Cardiovascular Imaging*. 2024;17(3):e016143.
43. Min JK, Chang HJ, Andreini D, et al. Coronary CTA plaque volume severity stages according to invasive coronary angiography and FFR. *J Cardiovasc Comput Tomogr*. 2022;16(5):415-422.
44. Deseive S, Kupke M, Straub R, et al. Quantified coronary total plaque volume from computed tomography angiography provides superior 10-year risk stratification. *European Heart Journal-Cardiovascular Imaging*. 2021;22(3):314-321.
45. Williams MC, Kwiecinski J, Doris M, et al. Sex-specific computed tomography coronary plaque characterization and risk of myocardial infarction. *Cardiovascular Imaging*. 2021;14(9):1804-1814.

46. Budoff MJ, Dowe D, Jollis JG, et al. Diagnostic performance of 64-multidetector row coronary computed tomographic angiography for evaluation of coronary artery stenosis in individuals without known coronary artery disease: results from the prospective multicenter ACCURACY (Assessment by Coronary Computed Tomographic Angiography of Individuals Undergoing Invasive Coronary Angiography) trial. *Journal of the American College of Cardiology*. 2008;52(21):1724-1732.
47. Jonas RA, Barkovich E, Choi AD, et al. The effect of scan and patient parameters on the diagnostic performance of AI for detecting coronary stenosis on coronary CT angiography. *Clin Imaging*. 2022;84:149-158.
48. Cho GW, Ghanem AK, Quesada CG, et al. Quantitative plaque analysis with A.I.-augmented CCTA in end-stage renal disease and complex CAD. *Clin Imaging*. 2022;89:155-161.
49. Jonas R, Earls J, Marques H, et al. Relationship of age, atherosclerosis and angiographic stenosis using artificial intelligence. *Open Heart*. 2021;8(2).
50. Tzimas G, Gulsin GS, Everett RJ, et al. Age-and sex-specific nomographic CT quantitative plaque data from a large international cohort. *JACC: Cardiovascular Imaging*. 2024;17(2):165-175.
51. Omori H, Matsuo H, Fujimoto S, et al. Determination of lipid-rich plaques by artificial intelligence-enabled quantitative computed tomography using near-infrared spectroscopy as reference. *Atherosclerosis*. 2023;386:117363.
52. Hakim D, Coskun AU, Maynard C, et al. Endothelial shear stress computed from coronary computed tomography angiography: A direct comparison to intravascular ultrasound. *Journal of Cardiovascular Computed Tomography*. 2023;17(3):201-210.
53. Grodecki K, Cadet S, Staruch AD, et al. Noncalcified plaque burden quantified from coronary computed tomography angiography improves prediction of side branch occlusion after main vessel stenting in bifurcation lesions: results from the CT-PRECISION registry. *Clin Res Cardiol*. 2021;110(1):114-123.
54. Narula J, Stuckey TD, Nakazawa G, et al. Prospective Deep Learning-based Quantitative Assessment of Coronary Plaque by CT Angiography Compared with Intravascular Ultrasound. *European Heart Journal-Cardiovascular Imaging*. 2024:jeae115.
55. Min JK, Dunning A, Lin FY, et al. Age-and sex-related differences in all-cause mortality risk based on coronary computed tomography angiography findings: results from the International Multicenter CONFIRM [Coronary CT Angiography Evaluation for Clinical Outcomes: An International Multicenter Registry] of 23,854 patients without known coronary artery disease. *Journal of the American College of Cardiology*. 2011;58(8):849-860.
56. Hadamitzky M, Achenbach S, Al-Mallah M, et al. Optimized prognostic score for coronary computed tomographic angiography: results from the CONFIRM registry (COronary CT Angiography EvaluatioN For Clinical Outcomes: An InteRnational Multicenter Registry). *J Am Coll Cardiol*. 2013;62(5):468-476.
57. Cho I, Al'Aref SJ, Berger A, et al. Prognostic value of coronary computed tomographic angiography findings in asymptomatic individuals: a 6-year follow-up from the prospective multicentre international CONFIRM study. *Eur Heart J*. 2018;39(11):934-941.
58. Chang HJ, Lin FY, Lee SE, et al. Coronary Atherosclerotic Precursors of Acute Coronary Syndromes. *J Am Coll Cardiol*. 2018;71(22):2511-2522.
59. van Rosendael AR, Narula J, Lin FY, et al. Association of High-Density Calcified 1K Plaque With Risk of Acute Coronary Syndrome. *JAMA Cardiol*. 2020;5(3):282-290.
60. Chang H-J, Lin FY, Gebow D, et al. Selective referral using CCTA versus direct referral for individuals referred to invasive coronary angiography for suspected CAD: a randomized, controlled, open-label trial. *JACC: Cardiovascular Imaging*. 2019;12(7 Part 2):1303-1312.
61. Kim Y, Choi AD, Telluri A, et al. Atherosclerosis Imaging Quantitative Computed Tomography (AI-QCT) to guide referral to invasive coronary angiography in the randomized controlled CONSERVE trial. *Clin Cardiol*. 2023;46(5):477-483.
62. Nurmohamed NS, Bom MJ, Jukema RA, et al. AI-Guided Quantitative Plaque Staging Predicts Long-

Term Cardiovascular Outcomes in Patients at Risk for Atherosclerotic CVD. *JACC: Cardiovascular Imaging*. 2023.
63. van Diemen PA, Bom MJ, Driessen RS, et al. Prognostic Value of RCA Pericoronary Adipose Tissue CT-Attenuation Beyond High-Risk Plaques, Plaque Volume, and Ischemia. *JACC Cardiovasc Imaging*. 2021;14(8):1598-1610.
64. Driessen RS, Bom MJ, van Diemen PA, et al. Incremental prognostic value of hybrid [15O] H2O positron emission tomography–computed tomography: Combining myocardial blood flow, coronary stenosis severity, and high-risk plaque morphology. *European Heart Journal-Cardiovascular Imaging*. 2020;21(10):1105-1113.
65. Rinehart S, Raible S, Ng N, Mullen S, Huey W, Pursnani A. Utility Of AI Plaque Quantification: Results Of The Decisions For Treating Coronary Disease Are Changed In Patients Evaluated With Quantified Plaque Analysis (DECODE) Study. *Journal of Cardiovascular Computed Tomography*. 2023;17(4):S33.
66. Nurmohamed NS, Cole JH, Budoff M, et al. Impact of Atherosclerosis Imaging-Quantitative Computed Tomography on Diagnostic Certainty, Downstream Testing, Coronary Revascularization and Medical Therapy: The CERTAIN Study. *Eur Heart J Cardiovasc Imaging*. 2024.
67. Park S-J, Ahn J-M, Kang D-Y, et al. Preventive percutaneous coronary intervention versus optimal medical therapy alone for the treatment of vulnerable atherosclerotic coronary plaques (PREVENT): a multicentre, open-label, randomised controlled trial. *The Lancet*. 2024;403(10438):1753-1765.
68. Freeman AM, Raman SV, Aggarwal M, et al. Integrating Coronary Atherosclerosis Burden and Progression with Coronary Artery Disease Risk Factors to Guide Therapeutic Decision Making. *Am J Med*. 2023;136(3):260-269 e267.
69. Kim C, Park CH, Lee BY, et al. 2024 Consensus Statement on Coronary Stenosis and Plaque Evaluation in CT Angiography From the Asian Society of Cardiovascular Imaging-Practical Tutorial (ASCI-PT). *Korean J Radiol.* 2024;25(4):331-342.
70. Howden N, Branch K, Douglas P, et al. Computed tomographic angiography measures of coronary plaque in clinical trials: opportunities and considerations to accelerate drug translation. *Front Cardiovasc Med*. 2024;11:1359500.
71. Schulman-Marcus J, Hartaigh B, Gransar H, et al. Sex-Specific Associations Between Coronary Artery Plaque Extent and Risk of Major Adverse Cardiovascular Events: The CONFIRM Long-Term Registry. *JACC Cardiovasc Imaging*. 2016;9(4):364-372.
72. 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*. 2019;139(25):e1162-e1177.
73. Blanke P, Naoum C, Ahmadi A, et al. Long-Term Prognostic Utility of Coronary CT Angiography in Stable Patients With Diabetes Mellitus. *JACC Cardiovasc Imaging*. 2016;9(11):1280-1288.
74. Andreini D, Conte E, Mushtaq S, et al. Plaque assessment by coronary CT angiography may predict cardiac events in high risk and very high risk diabetic patients: A long-term follow-up study. *Nutr Metab Cardiovasc Dis*. 2022;32(3):586-595.
75. Lo J, Lu MT, Ihenachor EJ, et al. Effects of statin therapy on coronary artery plaque volume and high-risk plaque morphology in HIV-infected patients with subclinical atherosclerosis: a randomised, double-blind, placebo-controlled trial. *Lancet HIV*. 2015;2(2):e52-63.
76. Lu MT, Ribaudo H, Foldyna B, et al. Effects of Pitavastatin on Coronary Artery Disease and Inflammatory Biomarkers in HIV: Mechanistic Substudy of the REPRIEVE Randomized Clinical Trial. *JAMA Cardiol*. 2024;9(4):323-334.
77. Fuchs A, Kühl JT, Sigvardsen PE, et al. Subclinical Coronary Atherosclerosis and Risk for Myocardial Infarction in a Danish Cohort : A Prospective Observational Cohort Study. *Ann Intern Med*. 2023;176(4):433-442.
78. Bax AM, van Rosendael AR, Ma X, et al. Comparative differences in the atherosclerotic disease burden

between the epicardial coronary arteries: quantitative plaque analysis on coronary computed tomography angiography. *Eur Heart J Cardiovasc Imaging*. 2021;22(3):322-330.

79. Motoyama S, Ito H, Sarai M, et al. Plaque Characterization by Coronary Computed Tomography Angiography and the Likelihood of Acute Coronary Events in Mid-Term Follow-Up. *J Am Coll Cardiol*. 2015;66(4):337-346.
80. Lee SE, Sung JM, Rizvi A, et al. Quantification of Coronary Atherosclerosis in the Assessment of Coronary Artery Disease. *Circ Cardiovasc Imaging*. 2018;11(7):e007562.
81. Local Coverage Determination (LCD) L39913, Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-QCT)/Coronary Plaque Analysis (AI-CPA)