Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

Cardiovascular Disease Risk Tests

Effective: January 1, 2026

Prior Authorization Required If REQUIRED, submit supporting documentation pertinent to service request to the FAX clinical numbers below	Yes ☐ No ☒
Notification Required IF REQUIRED, concurrent review may apply	Yes ☐ No ☒

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; 800-232-0816
☒ Tufts Health Plan Commercial products; 617-972-9409

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055
☒ Tufts Health Together – MassHealth Accountable Care Partnership Plans; 888-415-9055
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404
☒ Tufts Health One Care – A dual-eligible product; 857-304-6304

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-972-9409
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-972-9409
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-972-9409

Note: While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

Overview

Management of risk factors for cardiovascular disease (CVD) may be considered primary prevention for those who have not previously experienced an atherosclerotic vascular event, and there are several diagnostic tests designed to help assess non-traditional risk factors for cardiovascular disease.

Clinical Guideline Coverage Criteria

The Plan considers cardiovascular risk testing as reasonable and medically necessary when used to predict the risk of recurrent events in those with coronary artery disease (CAD) so that applicable interventions can be introduced and improved.

Limitations

The Plan does not cover the following as they are non-covered or investigational due to insufficient evidence of efficacy:

1. Advanced and novel lipoprotein analysis (subfractions, apolipoproteins,) for evaluation of cardiovascular risk

2. Multi-protein diagnostic biomarker, such as 3 proteins (high sensitivity [hs] troponin, adiponectin, and kidney injury molecule-1 [KIM-1]) or 4 proteins (NT-proBNP, osteopontin, tissue inhibitor of metalloproteinase-1 [TIMP-1], and KIM-1) with algorithm and reported as a risk score

3. Cardiovascular disease risk panels, consisting of multiple individual biomarkers intended to assess cardiac risk to include lipid and non-lipid cardiovascular risk markers such as:
    a. Long-chain omega-3 fatty acids for cardiovascular risk testing
    b. LDL subclass (e.g., Boston Heart Cholesterol Balance® Test)
    c. Lipoprotein (e.g., direct measurement, intermediate density lipoproteins (IDL) remnant lipoproteins)
    d. Lipoprotein- associated phospholipase ($LP\text{-}PLA_2$)
4. Arterial compliance testing using waveform analysis to determine cardiovascular risk
5. Carotid intima-media thickness (CIMT) measurement
6. Endothelial function assessment tools (e.g., peripheral arterial tonometry, brachial artery pressure ultrasound)

Please refer to the Noncovered and Investigational Services MNG

References:

1. Consensus Statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the Management of Dyslipidemia and Prevention of Cardiovascular Disease Algorithm – 2020 Executive Summary. Handelsman, Yehuda et al. Endocrine Practice , Volume 26, Issue 10, 1196 - 1224
2. ATP III Guidelines At-A-Glance Quick Desk Reference. 2001. Available at: https://www.nhlbi.nih.gov/files/docs/guidelines/atglance.pdf. Accessed December 11, 2024.
3. Benderly M, Boyko V, Goldbourt U. Apolipoproteins and long-term prognosis in coronary heart disease patients. Am Heart J. 2009; 157(1):103-10.
4. Biswas S, Ghoshal PK, Mandal SC, et al. Association of low-density lipoprotein particle size and ratio of different lipoproteins and apolipoproteins with coronary heart disease. J Cardiol. 2008;52(2):118-26.
5. Brunzell JD, Davidson M, Furberg CD, et al. Lipoprotein management in patients with cardiometabolic risk: consensus conference report from the American Diabetes Association and the American College of Cardiology Foundation. J Am Coll Cardiol. 2008;51(15):1512-24.
6. Cesari M, Rossi GP, Pessina AC. Homocysteine-lowering treatment in coronary heart disease. Curr Med Chem Cardiovasc Hematol Agents. 2005;3(4):289-95.
7. Connelly MA, Otvos JD, Shalaurova I, et al. GlycA, a novel biomarker of systemic inflammation and cardiovascular disease risk. Journal of Translational Medicine. 2017;15:219.
8. Coronary Heart Disease Risk Factors. 2014. Available at: https://www.nhlbi.nih.gov/health-topics/coronary-heart-disease-risk-factors. Accessed February 2, 2021.
9. Cromwell WC, Otvos JD. Heterogeneity of low-density lipoprotein particle number in patients with type 2 diabetes mellitus and low-density lipoprotein cholesterol <100 mg/dl. Am J Cardiol. 2006;98(12):1599-602.
10. Davidson MH, Corson MA, Alberts MJ, et al. Consensus Panel Recommendation for Incorporating Lipoprotein-Associated Phospholipase a Testing into Cardiovascular Disease Risk Assessment Guidelines. Am J Cardiol. 2008;101(12A Supp).
11. DeBacker G, Ambrosioni E, Borch-Johnsen K. European guidelines on cardiovascular disease prevention in clinical practice. third joint task force of european and other societies on cardiovascular disease prevention in clinical practice. ACC Current Journal Review. 2004;13(2):19. doi:10.1016/j.accreview.2003.12.022.
12. Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). 2001. Available at: https://www.nhlbi.nih.gov/files/docs/guidelines/atp3xsum.pdf. Accessed February 2, 2021.
13. Di Angelantonio E, Chowdhury R, Sarwar N et al. B-Type Natriuretic Peptides and Cardiovascular Risk: Systematic Review and Meta-Analysis of 40 Prospective Studies. 2009. Available at: http://circ.ahajournals.org/content/120/22/2177.long. Accessed February 2, 2021.
14. Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents: Summary Report. 2012. Available at: https://www.nhlbi.nih.gov/files/docs/guidelines/peds_guidelines_full.pdf. Accessed February 2, 2021.
15. Folsom A, Chambless L, Ballantyne C et al. An Assessment of Incremental Coronary Risk Prediction Using C-Reactive Protein and Other Novel Risk Markers. Arch Intern Med. 2006;166(13):1368. doi:10.1001/archinte.166.13.1368.
16. Folsom AR, Pankow JS, Tract RP, et al. Association of C-reactive protein with markers of prevalent atherosclerotic disease. Am J Cardiol. 2001;88(2): 112-7.
17. Giacobbe DT, Murray MJ. Vascular disease and inflammation. Anethesiology Clin N Am. 2004;22(2):183-97v.
18. Goff D, Lloyd-Jones D, Bennett G et al. 2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk. 2014. Available at: http://circ.ahajournals.org/content/129/25_suppl_2/S49.long. Accessed February 2, 2021.
19. Gotto AM Jr, Whitney E, Stein EA, et al. Relation between baseline and on-treatment lipid parameters and first acute major coronary events in the Air Force/Texas Coronary Atherosclerosis Prevention Study (AFCAPS/TexCAPS).

Circulation. 2000;101(5):477-84.
20. Greenland P, Alpert J, Beller G et al. ACCF/AHA Guideline for Assessment of Cardiovascular Risk in Asymptomatic Adults: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. 2010. Available at: https://www.ahajournals.org/doi/10.1161/CIR.0b013e3182051bab. Accessed December 11, 2024.
21. Grundy SM, Pasternak R, Greenland P, et al. Assessment of cardiovascular risk by use of multiple-risk-factor equations. A Statement for Healthcare Professionals from the American Heart Association and the American College of Cardiology. AHA/ACC Scientific Statement. J Am Coll Cardiol. 199;34(4):1348-59.
22. Hayesinc.com/login [via subscription only]. Accessed February 2, 2021.
23. High sensitivity cardiac troponin assays. Journal of American College of Cardiology. 2017;55(s2). doi:10.1515/cclm-2017-7053.
24. High-Sensitivity C-reactive protein Measurement for Coronary Heart Disease Risk Stratification. Assessment Program Volume 17, No. 23. BCBS. Technology Evaluation Center, Special Report. BCBS. Published on May 2003.
25. High-Sensitivity C-Reactive Protein Testing for Diagnosis and Management of Coronary Artery Disease. Hayesinc.com/login [via subscription only]. Accessed February 2, 2021.
26. Holme I, Cater NB, Faergeman O, et al. Incremental Decrease in End-Points Through Aggressive Lipid-Lowering (IDEAL) Study Group. Lipoprotein predictors of cardiovascular events in statin-treated patients with coronary heart disease. Insights from the Incremental Decrease in End-points Through Aggressive Lipid-lowering Trial (IDEAL). Ann Med. 2008;40(6):456-64.
27. Ingelsson E, Schaefer EJ, Contois JH, et al. Clinical utility of different lipid measures for prediction of coronary heart disease in men and women. JAMA. 2007;298(7):776-85.
28. Jacobson T, Ito M, Maki K et al. National Lipid Association Recommendations for Patient-Centered Management of Dyslipidemia: Part 1—Full Report. J Clin Lipidol. 2015;9(2):129-169. doi:10.1016/j.jacl.2015.02.003.
29. Jafri H, Alsheikh-Ali A, Mooney P, et al. Extended-release niacin reduces LDL particle number without changing total LDL cholesterol in patients with stable CAD. Journal of Clinical Lipidology. 2009:3(1):45-50.
30. Kastelein JJ, van der Steeg WA, Holme I, et al. TNT Study Group; IDEAL Study Group. Lipids, apolipoproteins, and their ratios in relation to cardiovascular events with statin treatment. Circulation. 2008;117(23):3002-9.
31. Khadem-Ansari MH, Rasmi Y, Rahimi-Pour A, et al. The association between serum apolipoprotein A-I and apolipoprotein B and the severity of angiographical coronary artery disease. Singapore Med J. 2009; 50(6): 610-3.
32. Koba S, Yokota Y, Hirano T, et al. Small LDL-cholesterol is superior to LDL-cholesterol for determining severe coronary atherosclerosis. Atheroscler Thromb. 2008;15(5):250-60.
33. Labarrere CA, Zaloga GP. C-reactive protein: from innocent bystander to pivotal mediator of atherosclerosis. Am J Med. 200;117:499-507.
34. Lamarche B, Moorjani S, Lupien PJ, et al. Apolipoprotein A-I and B Levels and the Risk of Ischemic Heart Disease During a Five-Year Follow-up of Men in the Quebec Cardiovascular Study. Circulation. 1996; 94:273-78.
35. Lau JF, Smith DA. Advanced lipoprotein testing: recommendations based on current evidence. Endocrinol Metab Clin North Am. 2009;38(1):1-31.
36. LDL particle number as assessed by NMR spectroscopy. California Technology Assessment Forum (CTAF). Published October 15, 2008.
37. Linton MF, Fazio S. A practical approach to risk assessment to prevent coronary artery disease and its complications. Am J Cardiol. 2003;92(1A):19i-26i.
38. Lipoprotein-associated phospholipase testing for coronary heart disease risk assessment in healthy or asymptomatic adults. Medical Technology Directory. Hayesinc.com/login [via subscription only]. Accessed February 2, 2021.
39. Lipoprotein-associated Phospholipase testing for stroke assessment in adults. Medical Technology Directory.
40. Low HDL Cholesterol (Hypoalphalipoproteinemia): Background, Pathophysiology, Epidemiology. 2016. Available at: https://emedicine.medscape.com/article/127943-overview. Accessed February 2, 2021.
41. Management of Elevated Low-Density Lipoprotein-cholesterol (LDL-C) in Primary Prevention of Cardiovascular Disease. UpToDate.com/login [via subscription only]. Accessed February 2, 2021.
42. Mangoni AA, Jackson SHD. Homocysteine and cardiovascular disease: current evidence and future prospects. Am J Med. 2002;112(7):556-65.
43. Mora S, Szklo M, Otvos JD, et al. LDL particle subclasses, LDL particle size, and carotid atherosclerosis in the Multi-Ethnic Study of Atherosclerosis (MESA). Atherosclerosis. 2007;192(1):211-7.
44. Morrow DA. C-reactive protein in cardiovascular disease. UpToDate.com/login [via subscription only]. Accessed February 2, 2021.
45. Morrow DA. C-reactive protein in cardiovascular disease. UpToDate.com/login [via subscription only]. Accessed February 2, 2021.
46. Myers GL, Christenson RH, Cushman M, et al. National Academy of Clinical Biochemistry Laboratory Medicine

Practice guidelines: emerging biomarkers for primary prevention of cardiovascular disease. NACB LMPG Committee. Published 2009.

47. Otvos JD, Collins D, Freedman DS, et al. Low-density lipoprotein and high-density lipoprotein particle subclasses predict coronary events and are favorably changed by gemfibrozil therapy in the Veterans Affairs High-Density Lipoprotein Intervention Trial. Circulation. 2006;113(12):1556-63.
48. Pearson TA, Mensah GA, Alexander RW, et al. Markers of inflammation and cardiovascular disease: application to clinical and public health practice: A statement for healthcare professionals from the Centers for Disease Control and Prevention and the American Heart Association. Circulation 2003;107:499.
49. Pejic RN, Jamieson B, Saseen J. Which lipoprotein measurements are clinically useful? Am Fam Physician. 2007;75(3):387-388.
50. Ray KK, Cannon CP, Cairns R, et al. Prognostic utility of apoB/AI, total cholesterol/HDL, non-HDL cholesterol, or hs-CRP as predictors of clinical risk in patients receiving statin therapy after acute coronary syndromes: results from PROVE IT-TIMI 22. Arterioscler Thromb Vasc Biol. 2009;29(3):424-30.
51. Ridker PM, Cannon CP, Morrow D, et al. C-reactive protein levels and outcomes after statin therapy. N Engl J Med. 2005;325:20-8.
52. Ridker PM, Hennekens CH, Buring JE, et al. C-reactive protein and other markers of inflammation in the prediction of cardiovascular disease in women. N Engl J Med. 2000;342(12):836-43.
53. Rosenson RS, Kang DS. Overview of homosysteine. UpToDate.com/login [via subscription only]. Accessed February 2, 2021.
54. Rosenson RS, Stein JH, Durrington P. Lipoprotein(a) and cardiovascular disease. UpToDate.com/login [via subscription only]. Accessed February 2, 2021.
55. Rosenson RS. Measurement of blood lipids and lipoproteins. UpToDate.com/login [via subscription only]. Accessed February 2, 2021.
56. Scirica BM, Morrow DA. Is C-reactive protein an innocent bystander or proatherogenic culprit? The verdict is still out. Circulation 2006;113:2128.
57. Screening for Dyslipidemia In Younger Adults: A Systematic Review To Update The 2008 U.S. Preventive Services Task Force Recommendation. United States Preventive Services Task Force (USPSTF); 2016. Available at: http://file:///C:/Users/jkim2/Downloads/dyslipidemia-evidencervw-final.pdf. Accessed February 2, 2021.
58. Screening for Lipid Disorders in Children: Recommendation Statement. U.S. Preventive Services Task Force. Agency for Healthcare Research and Quality. Published July 2007.
59. Sharrett AR, Ballantyne CM, Coady SA, et al. Atherosclerosis Risk in Communities Study Group. Coronary heart disease prediction from lipoprotein cholesterol levels, triglycerides, lipoprotein(a), apolipoproteins A-I and B, and HDL density subfractions: The Atherosclerosis Risk in Communities (ARIC) Study. Circulation. 2001;104(10):1108-13.
60. Sierra-Johnson J, Fisher RM, Romero-Corral A, et al. Concentration of apolipoprotein B is comparable with the apolipoprotein B/apolipoprotein A-I ratio and better than routine clinical lipid measurements in predicting coronary heart disease mortality: findings from a multi-ethnic US population. Eur Heart J. 2009;30(6):710-7.
61. Sniderman AD, Furberg CD, Keech A, et al. Apolipoproteins versus lipids as indices of coronary risk and as targets for statin treatment. Lancet. 2003a;361(9359):777-80.
62. Splaver A, Lamas GA, Hennekens CH. Homocysteine and cardiovascular disease: biological mechanisms, observational epidemiology, and the need for randomized trials. Am Heart J. 2004;148(1):3440.
63. Stampfer MJ, Sacks FM, Salvini S, et al. A prospective study of cholesterol, apolipoproteins, and the risk of myocardial infarction. N Engl J Med. 1991;325-6:373-81.
64. Third report of the panel on detection, evaluation, and treatment of high blood cholesterol in adults (Adult Treatment Panel III). Risk assessment tool for estimating 10-year risk of developing hard CHD (myocardial infarction and coronary death). National Cholesterol Education Program.
65. Using Nontraditional Risk Factors in Coronary Heart Disease Risk Assessment, Topic Page. U.S. Preventive Services Task Force. Published October 2009.
66. von Haehling S, Doehner W, Jankowska E et al. Value of serum pregnancy-associated plasma protein A for predicting cardiovascular events among patients presenting with cardiac chest pain. Can Med Assoc J. 2013;185(7):E295-E303. doi:10.1503/cmaj.110647.
67. Wallach J. Serum apolipoproteins. In: Seigafuse S, ed. Interpretation of diagnostic tests. Cardiovascular diseases. Diseases principally of endocardium. Lippincott Williams & Wilkins; 2007.
68. Yeh ET. High-sensitivity C-reactive protein as a risk assessment tool for cardiovascular disease. Clin Cardiol. 2005;28(9):408-412.
69. Yin WH, Chen JW, Jen HL, et al. Independent prognostic value of elevated high-sensitivity C-reactive protein in chronic heart failure. Am Heart J. 2004;147(5):931-8.
70. Zacho J, Tybjaerg-Hansen A, Jensen JS, et al. Genetically elevated C-reactive protein and ischemic vascular disease. N Engl J Med. 2008;359(18):1897-908

Approval And Revision History

December 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC) for integration between Harvard Pilgrim Health Care and Tufts Health Plan. Coverage guideline created to outline medical necessity for cardiovascular disease risk tests. Effective July 7, 2023
Subsequent endorsement date(s) and changes:

- November 16, 2023: Reviewed by MPAC, renewed without changes
- November 2023: Unify name changed to One Care effective January 1, 2024
- November 21, 2024: Reviewed by MPAC, renewed without changes, effective January 1, 2025
- December 13, 2024: Reviewed and approved by the UM Committee, effective January 1, 2025
- November 19, 2025: Reviewed by MPAC for annual review, renewed without changes effective January 1, 2026
- December 2025: Administrative updates effective January 1, 2026
- December 8, 2025: Reviewed by UM Committee for annual review, renewed without changes effective January 1, 2026

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.