

Reimbursement Policy

Cardiovascular Disease Risk Assessment

[POLICY DESCRIPTION](#) | [INDICATIONS AND/OR LIMITATIONS OF COVERAGE](#) | [APPLICABLE STATE AND FEDERAL REGULATIONS](#) | [APPLICABLE CPT/HCPCS PROCEDURE CODES](#) | [EVIDENCE-BASED SCIENTIFIC REFERENCES](#) |

I. Policy Description

Cardiovascular risk assessment comprises the means and processes to predict the probability of developing a cardiovascular disease. These are a group of tests and health factors that have been proven to indicate a person's chance of having a cardiovascular event such as a heart attack or stroke.

Tests typically used to assess cardiovascular risk include lipid profiles or panels, biomarkers, and cardiovascular risk panels.

For guidance concerning lipid screening in individuals under 18 years of age, please refer to AHS-G2042-Pediatric Preventive Screening.

For guidance concerning homocysteine testing for indications other than cardiovascular disease, please refer to AHS-M2141-Testing of Homocysteine Metabolism-Related Conditions and AHS-G2014-Vitamin B12 and Methylmalonic Acid Testing.

Terms such as male and female are used when necessary to refer to sex assigned at birth.

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

- 1) For individuals 18 years of age or older, lipid panel testing (see Note 1) **MEETS COVERAGE CRITERIA** under **any** of the following conditions:
 - a) To screen for cardiovascular disease (CVD) risk:
 - i) Annually for individuals ages 18 to 79 years.
 - ii) Annually for individuals at increased risk for cardiovascular disease (as defined by 2013 ACC/AHA Pooled Cohort Equations (PCEs) to calculate 10-year risk of CVD events [see Note 2]).
 - b) Annually for individuals at an increased risk of dyslipidemia due to **any** of the following conditions:
 - i) Obesity or metabolic syndrome
 - ii) Nephrotic syndrome

Reimbursement Policy

- iii) Hypothyroidism
 - iv) Hyperthyroidism
 - v) Pancreatitis
 - vi) Diabetes
 - vii) Chronic kidney disease
 - viii) Cushing syndrome
 - ix) Pregnancy
 - x) Cholestatic liver disease
 - xi) Lipid metabolism disorders, such as Gaucher disease in adults
- c) For individuals who are about to begin or who are currently receiving statin therapy, at the following intervals:
- i) To establish baseline levels before initiating statin therapy.
 - ii) Every four to twelve weeks after initiation or change of therapy.
 - iii) Annually when no medication changes have occurred.
- d) Annually for individuals on a long-term drug therapy that requires lipid monitoring (e.g., Accutane, anti-psychotics).
- e) For HIV positive individuals who are about to begin or who are currently receiving antiretroviral therapy (ART), at the following intervals:
- i) To establish baseline levels before initiating ART.
 - ii) Every one to three months after initiation or change of therapy.
 - iii) Every six to twelve months when no medication changes have occurred.
- 2) Measurement of apolipoprotein B (apoB) **MEETS COVERAGE CRITERIA** for **any** of the following situations:
- a) For individuals with hypertriglyceridemia.
 - b) For individuals with diabetes mellitus.
 - c) For individuals with obesity or metabolic syndrome.
 - d) For individuals with other dyslipidemias (such as very low LDL-C).
 - e) For individuals who are on lipid therapy.
 - f) For individuals who are suspected to have familial dysbetalipoproteinemia or familial combined hyperlipidemia.
- 3) For individuals 18 years of age or older, measurement of lipoprotein a (Lp(a)) once per lifetime **MEETS COVERAGE CRITERIA**.
- 4) For individuals for whom a risk-based treatment decision is uncertain (after quantitative risk assessment using ACC/AHA PCEs to calculate 10-year risk of CVD events [see Note 2]), testing for C-reactive protein with the high-sensitivity method (hs-CRP) **MEETS COVERAGE CRITERIA** at the following frequency:
- a) For initial screening, two measurements at least two weeks apart.
 - b) If the initial screen was abnormal, follow-up screening is allowed up to once per year.

The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.

Reimbursement Policy

- 5) For all other cardiovascular disease risk assessments not described above, testing for CRP **DOES NOT MEET COVERAGE CRITERIA.**
- 6) For CVD risk assessment and stratification in the outpatient setting, measurement of high-sensitivity cardiac troponin T (hs-cTnT) **DOES NOT MEET COVERAGE CRITERIA.**
- 7) For CVD risk assessment screening, evaluation, and management, homocysteine testing **DOES NOT MEET COVERAGE CRITERIA.**
- 8) For CVD risk assessment, measurement of novel lipid and non-lipid biomarkers (e.g., apolipoprotein AI, apolipoprotein E, B-type natriuretic peptide, cystatin C, fibrinogen, leptin, LDL subclass, HDL subclass) **DOES NOT MEET COVERAGE CRITERIA.**
- 9) Other than simple lipid panels (see Note 1), CVD risk panels consisting of multiple individual biomarkers intended to assess CVD **DO NOT MEET COVERAGE CRITERIA.**
- 10) For CVD risk assessment, measurement of serum intermediate density lipoproteins **DOES NOT MEET COVERAGE CRITERIA.**
- 11) For CVD risk assessment, measurement of lipoprotein-associated phospholipase A2 (Lp-PLA2) **DOES NOT MEET COVERAGE CRITERIA.**
- 12) For all situations, measurement of long-chain omega-3 fatty acids in red blood cell membranes, **DOES NOT MEET COVERAGE CRITERIA.**
- 13) All other tests for assessing CVD risk **DO NOT MEET COVERAGE CRITERIA.**

NOTES:

Note 1: A simple lipid panel is generally composed of the following lipid markers:

- Total cholesterol
- HDL cholesterol
- LDL cholesterol
- Triglycerides

Certain calculated ratios, such as the total/HDL cholesterol may also be reported as part of a simple lipid panel.

Other types of lipid testing (i.e., apolipoproteins, lipid particle number or particle size, lipoprotein [a]) are not considered to be components of a simple lipid profile.

Note 2: 2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk (Goff et al., 2014): Risk factors include gender, age, race, smoking, hypertension, diabetes, total cholesterol, high- and low-density lipoprotein cholesterol. A race- and sex-specific PCE ASCVD Risk Estimator is available at:

https://tools.acc.org/ldl/ascvd_risk_estimator/index.html#!/calculate/estimator/.

The 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol affirms that “the PCE is a powerful tool to predict population risk, but it has limitations when applied to individuals.” Hence a clinician-patient risk discussion can individualize risk status based on PCE, but with the inclusion of

Reimbursement Policy

additional risk-enhancing factors. These additional factors may include:

- A family history of premature ASCVD (males, age <55 y; females, age <65 y)
- Primary hypercholesterolemia (LDL-C, 160–189 mg/dL [4.1–4.8 mmol/L]; non-HDL-C 190–219 mg/dL [4.9–5.6 mmol/L])
- Metabolic syndrome (increased waist circumference, elevated triglycerides [>150 mg/dL], elevated blood pressure, elevated glucose, and low HDL-C [<40 mg/dL in men; <50 in women mg/dL] are factors; tally of 3 makes the diagnosis)
- Chronic kidney disease (eGFR 15–59 mL/min/1.73 m² with or without albuminuria; not treated with dialysis or kidney transplantation)
- Chronic inflammatory conditions such as psoriasis, RA, or HIV/AIDS
- History of premature menopause (before age 40 y) and history of pregnancy-associated conditions that increase later ASCVD risk such as preeclampsia
- High-risk race/ethnicities (eg, South Asian ancestry)
- Lipid/biomarkers: Associated with increased ASCVD risk
- Persistently elevated, primary hypertriglyceridemia (≥ 175 mg/dL)
- Elevated high-sensitivity C-reactive protein (≥ 2.0 mg/L)
- Elevated Lp(a): A relative indication for its measurement is family history of premature ASCVD. An Lp(a) ≥ 50 mg/dL or ≥ 125 nmol/L constitutes a risk-enhancing factor especially at higher levels of Lp(a)
- Elevated apoB ≥ 130 mg/dL: A relative indication for its measurement would be triglyceride ≥ 200 mg/dL. A level ≥ 130 mg/dL corresponds to an LDL-C ≥ 160 mg/dL and constitutes a risk-enhancing factor
- ABI <0.9

III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: <https://www.cms.gov/medicare-coverage-database/search.aspx>. For the most up-to-date Medicaid policies and coverage, visit the applicable state Medicaid website.

Food and Drug Administration (FDA)

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

Reimbursement Policy

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
80061	Lipid panel
81599	Unlisted multianalyte assay with algorithmic analysis
82172	Apolipoprotein, each
82465	Cholesterol, serum or whole blood, total
82610	Cystatin C
83090	Homocysteine
83695	Lipoprotein (a)
83698	Lipoprotein-associated phospholipase A2 (Lp-PLA2)
83700	Lipoprotein, blood; electrophoretic separation and quantitation
83701	Lipoprotein, blood; high resolution fractionation and quantitation of lipoproteins including lipoprotein subclasses when performed (eg, electrophoresis, ultracentrifugation)
83704	Lipoprotein, blood; quantitation of lipoprotein particle number(s) (eg, by nuclear magnetic resonance spectroscopy), includes lipoprotein particle subclass(es), when performed
83718	Lipoprotein, direct measurement; high density cholesterol (HDL cholesterol)
83719	Lipoprotein, direct measurement; VLDL cholesterol
83721	Lipoprotein, direct measurement; LDL cholesterol
83722	Lipoprotein, direct measurement; small dense LDL cholesterol
83880	Natriuretic peptide
84478	Triglycerides
84484	Troponin, quantitative
84512	Troponin, Qualitative
84999	Unlisted chemistry procedure
85384	Fibrinogen; activity
85415	Fibrinolytic factors and inhibitors; plasminogen activator
86140	C-reactive protein
86141	C-reactive protein; high sensitivity (hsCRP)
0019M	Cardiovascular disease, plasma, analysis of protein biomarkers by aptamer based microarray and algorithm reported as 4-year likelihood of coronary event in high-risk populations Proprietary test: SOMAmer® Lab/Manufacturer: SomaLogic

Reimbursement Policy

CPT	Code Description
0052U	Lipoprotein, blood, high resolution fractionation and quantitation of lipoproteins, including all five major lipoprotein classes and subclasses of HDL, LDL, and VLDL by vertical auto profile ultracentrifugation Proprietary test: VAP Cholesterol Test Lab/Manufacturer: VAP Diagnostics Laboratory, Inc
0377U	Cardiovascular disease, quantification of advanced serum or plasma lipoprotein profile, by nuclear magnetic resonance (NMR) spectrometry with report of a lipoprotein profile (including 23 variables) Proprietary test: Liposcale® Lab/Manufacturer: CIMA Sciences, LLC
0415U	Cardiovascular disease (acute coronary syndrome [ACS]), IL-16, FAS, FASLigand, HGF, CTACK, EOTAXIN, and MCP-3 by immunoassay combined with age, sex, family history, and personal history of diabetes, blood, algorithm reported as a 5-year (deleted risk) score for ACS Proprietary test: SmartHealth Vascular Dx™ Lab/Manufacturer: Morningstar Laboratories, LLC

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Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

V. Evidence-based Scientific References

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Reimbursement Policy

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