NO. 91559-R7

CARDIOVASCULAR RISK MARKERS

Effective date: 03/01/2026 **Last reviewed**: 02/2026

Instructions for use: This document is for informational purposes only. Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion. Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

Policy scope: This policy addresses the measurement of risk markers (biomarkers), other than total cholesterol or lipoproteins, to assess cardiovascular risk.

Related policies:

- Genetics: Counseling, Testing and Screening # 91540

SUMMARY OF CHANGES – R7

Additions:

- New Policy scope section
- New Medical/Professional Society Guidelines section
- New Government Regulations section listing applicable CMS NCDs or LCDs
- New FDA/Regulatory section

I. MEDICAL NECESSITY CRITERIA

A. INCLUSIONS: In addition to traditional risk assessment, the following cardiovascular disease (CVD) risk markers are considered medically necessary:

1. Lipoprotein-associated phospholipase A2 (Lp-PLA2) (PLAC), limited to one test per year.
2. High-sensitivity C-reactive protein (hs-CRP) if both of the following apply:

a. Using the 10-year risk assessment tool recommended by the National Cholesterol Education Program (NCEP), the patient is at intermediate risk of developing coronary heart disease (CHD (i.e.10-year risk of 10–20%).
b. The patient is metabolically stable without obvious inflammatory or infectious conditions.

3. Apolipoprotein B (apo B)
4. Lipoprotein(a) enzyme immunoassay

B. EXCLUSIONS: The medical literature does not support the utility of the following tests for screening, diagnosis, or management of CVD and they are therefore considered not medically necessary:

1. Apolipoprotein A-I (apo AI)
2. Apolipoprotein E (apo E)
3. Homocysteine testing
4. LDL gradient gel electrophoresis
5. Angiotensin gene (CardiaRisk™ AGT)
6. Measurement of long chain omega-3 fatty acids
7. Interleukin 6 -174 g/c promoter polymorphism
8. Carotid intimal-media thickness
9. LipiScan IVUS Coronary Imaging System (fat composition of plaque)
10. Prothrombotic factors (e.g., plasminogen activator inhibitor [PAI–1], activated factor VII, tissue plasminogen activator [tPA], von Willebrand factor, factor V Leiden, protein C, antithrombin III, fibrinogen)
11. Skin cholesterol test (PREVU Point of Care (POC) Skin Sterol Test, PreMD Inc.)
12. Lipoprotein particle size and concentration/density measurement (e.g., NMR LipoProfile® test)
13. Natriuretic peptides
14. Peripheral arterial tonometry, endothelial function test (e.g. EndoPAT™)
15. Gene expression analysis (e.g. Corus® CAD)
16. Secretory type II phospholipase A2 (sPLA2-IIA)
17. Singulex SMC™ testing for risk of cardiac dysfunction and vascular inflammation (e.g. SMC Endothelin, SMC IL-6, SMC IL 17A, SMC c TnI and SMC TNF-α).

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
None identified	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	B-Type Natriuretic Peptide (BNP) Testing L33943 A56425 MolDX: Biomarkers in Cardiovascular Risk Assessment L36139 A57386 MolDX: Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR) L35984 A56980 MolDX: Molecular Diagnostic Tests L36021 A56973 MolDX: Repeat Germline Testing L38288 A57141
First Coast Service Options, Inc.	B-Type Natriuretic Peptide (BNP) L33267 A57649 Genetic Testing For Cardiovascular Disease L39084 A58797 Molecular Pathology Procedures L34519 A57451
National Government Services, Inc.	B-Type Natriuretic Peptide (BNP) Testing L33573 A56826 Molecular Pathology Procedures L35000 A56199
Noridian Healthcare Solutions	B-Type Natriuretic Peptide (BNP) Testing L34038 A57084 L35526 A57083 MolDX: Biomarkers in Cardiovascular Risk Assessment L36358 A57037 Brain Natriuretic Peptide (BNP) Level MolDX: Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR) L36155 A57423 L36159 A57424 MolDX: Molecular Diagnostic Tests L35160 A57526 L36256 A57527 MolDX: Repeat Germline Testing L38351 A57331 L38353 A57332
Novitas Solutions, Inc.	Assays for Vitamins and Metabolic Function L34914 A56416 Biomarkers Overview L35062 A56541 Genetic Testing for Cardiovascular Disease L39082 A58795
Palmetto GBA	B-Type Natriuretic Peptide (BNP) Testing L34410 A56605 MolDX: Biomarkers in Cardiovascular Risk Assessment L36129 A56943 Brain Natriuretic Peptide (BNP) Level L33422 A56565

	MolDX: Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR) L36089 A56899 MolDX: Molecular Diagnostic Tests L35025 A56853 MolDX: Repeat Germline Testing L38274 A58017
WPS Insurance Corporation	MolDX: Biomarkers in Cardiovascular Risk Assessment L36523 A57559 MolDX: Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR) L36400 A57571 MolDX: Molecular Diagnostic Tests L36807 A57772 MolDX: Repeat Germline Testing L38429 A57100

III. BACKGROUND

Determination of cardiovascular disease (CVD) risk is based on standard, accepted risk-stratification approaches. These approaches are based on global assessment and traditional risk factor assessment including cholesterol/low density lipoprotein levels (LDL), diet, smoking, diabetes and family and personal medical history. The National Cholesterol Education Program (NCEP) utilizes the Framingham risk scoring calculation, endorsed by the National Heart Lung and Blood Institute (NHLBI) and the AHA for determining 10-year coronary heart disease (CHD) risk.

Newer generation cardiovascular risk markers are developed and proposed to enhance the prediction of cardiovascular disease. Evaluation of the potential clinical utility of these emerging tests includes the following:

- Does the test better identify those at higher risk than the current risk scores (Framingham risk score)?
- Does treatment differ for those at highest risk?
- Does treatment improve clinical outcomes?

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
American Heart Association	Next Generation, Modifiable Cardiometabolic Biomarkers: Mitochondrial Adaptation and Metabolic Resilience: A Scientific Statement From the American Heart Association (2023) Future Perspectives of Cardiovascular Biomarker Utilization in Cancer Survivors: A Scientific Statement From the American Heart Association (2021)

	Lipoprotein(a): A Genetically Determined, Causal, and Prevalent Risk Factor for Atherosclerotic Cardiovascular Disease: A Scientific Statement From the American Heart Association (2021) Genetic Testing for Inherited Cardiovascular Diseases: A Scientific Statement From the American Heart Association (2020) Role of Biomarkers for the Prevention, Assessment, and Management of Heart Failure: A Scientific Statement From the American Heart Association (2017)
American College of Cardiology	2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease (2019)
National Lipid Association	LDL cholesterol management simplified in adults—lower for longer is better: Guidance from the National Lipid Association (2025) Role of apolipoprotein B in the Clinical Management of Cardiovascular Risk in Adults: An Expert Clinical Consensus from the National Lipid Association (06-Sep-2024) A Focused Update to the 2019 NLA Scientific Statement on Use of Lipoprotein(a) in Clinical Practice (07-Mar-2024) The Importance of Low-Density Lipoprotein Cholesterol Measurement and Control as Performance Measures: A Joint Clinical Perspective from the National Lipid Association and the American Society for Preventive Cardiology (27-Feb-2023) Lipid Measurements in the Management of Cardiovascular Diseases: Scientific Statement (02-Sep-2021) Genetic testing in dyslipidemia: A scientific statement from the National Lipid Association (2020)

	Use of Lipoprotein(a) in Clinical Practice: A Biomarker Whose Time Has Come. A Scientific Statement from the National Lipid Association (29-Apr-2019) Clinical Utility of Inflammatory Markers & Advanced Lipoprotein Testing: Advice from Lipid Specialists (2011) Familial Hypercholesterolemia: Screening, Diagnosis and Management of Pediatric and Adult Patients (2011)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

CLIA - Clinical Laboratory Improvement Amendments - Currently Waived Analytes

This is a list of analytes that are used in laboratory test systems that have been "waived". Under the current process, waiver may be granted to:

1) any test listed in the regulation,

2) any test system for which the manufacturer or producer applies for waiver if that test meets the statutory criteria and the manufacturer provides scientifically valid data verifying that the waiver criteria have been met, and

3) test systems cleared by the FDA for home use.

The waived analytes listed are linked to waived test systems. Waived analytes relevant to this medical policy include the following:

- LDL cholesterol
- HDL cholesterol
- B-type natriuretic peptide (BNP)
- Triglyceride
- Cholesterol

VI. CODING

See also Priority Health Billing Policy No. 132 – Cardiovascular Disease Risk Assessment

ICD-10 Codes that may support medical necessity

E71.30	Disorder of fatty-acid metabolism, unspecified
E75.21	Fabry (-Anderson) disease
E75.22	Gaucher disease
E75.240	Niemann-Pick disease type A
E75.241	Niemann-Pick disease type B
E75.242	Niemann-Pick disease type C

E75.243	Niemann-Pick disease type D
E75.248	Other Niemann-Pick disease
E75.249	Niemann-Pick disease, unspecified
E75.3	Sphingolipidosis, unspecified
E75.5	Other lipid storage disorders
E75.6	Lipid storage disorder, unspecified
E77.0–E77.9	Disorders of glycoprotein metabolism
E78.00–E78.9	Disorders of lipoprotein metabolism and other lipidemias
E88.1	Lipodystrophy, not elsewhere classified
E88.2	Lipomatosis, not elsewhere classified
E88.89	Other specified metabolic disorders

F17.200–F17.299	Nicotine dependence

I10	Essential (primary) hypertension
I11.0–I11.9	Hypertensive heart disease
I12.0–I12.9	Hypertensive chronic kidney disease
I16.0 – I16.9	Hypertensive crisis

Z82.49	Family history of ischemic heart disease and other diseases of the circulatory system

May be preventive:

Z00.00-Z00.01	Encounter for general adult medical examination
Z00.121-Z00.129	Encounter for routine child health examination
Z13.220	Encounter for screening for lipoid disorders
Z01.411-Z01.419	Encounter for gynecological examination
Z13.6	Encounter for screening for cardiovascular disorders

CPT/HCPCS Codes
See criteria above for coverage information.

81493	Coronary artery disease, mRNA, gene expression profiling by real-time RT-PCR of 23 genes, utilizing whole peripheral blood, algorithm reported as a risk score Corus® CAD (PA required)
82172	Apolipoprotein, each
83695	Lipoprotein (a)
83698	Lipoprotein-associated phospholipase A2 (Lp-PLA2)
83719	Lipoprotein, direct measurement; VLDL cholesterol
83722	Lipoprotein, direct measurement; small dense LDL cholesterol
86141	C-reactive protein; high sensitivity (hsCRP)
84999	Unlisted chemistry procedure

(Explanatory notes must accompany claims billed with unlisted codes.)

May be preventive

80061 Lipid panel This panel must include the following: Cholesterol, serum, total (82465) Lipoprotein, direct measurement, high density cholesterol (HDL cholesterol) (83718) Triglycerides (84478)
82465 Cholesterol, serum or whole blood, total
83718 Lipoprotein, direct measurement; high density cholesterol (HDL cholesterol)
83721 Lipoprotein, direct measurement; LDL cholesterol
84478 Triglycerides

Not covered for screening
See also Policy# 91540 Genetics: Counseling, Testing and Screening
81240 F2 (prothrombin, coagulation factor II) (e.g., hereditary hypercoagulability) gene analysis, 20210G>A variant
81241 F5 (coagulation Factor V) (e.g., hereditary hypercoagulability) gene analysis, Leiden variant
82615 Cystine and homocystine, urine, qualitative
83090 Homocysteine
85300 Clotting inhibitors or anticoagulants; antithrombin III, activity
85303 Clotting inhibitors or anticoagulants; protein C, activity
85384 Fibrinogen; activity
85385 Fibrinogen; antigen
85415 Fibrinolytic factors and inhibitors; plasminogen activator
85420 Fibrinolytic factors and inhibitors; plasminogen, except antigenic assay
85421 Fibrinolytic factors and inhibitors; plasminogen, antigenic assay
83700 Lipoprotein, blood; electrophoretic separation and quantitation
83701 Lipoprotein, blood; high resolution fractionation and quantitation of lipoproteins including lipoprotein subclasses when performed (e.g., electrophoresis, ultracentrifugation)
83704 Lipoprotein, blood; quantitation of lipoprotein particle number(s) (e.g., by nuclear magnetic resonance spectroscopy), includes lipoprotein particle subclass (es), when performed
83880 Natriuretic peptide

Not covered for any dx
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
0308U Cardiology (coronary artery disease [CAD]), analysis of 3 proteins (high sensitivity [hs] troponin, adiponectin, and kidney injury molecule-1 [KIM-1]), plasma, algorithm reported as a risk score for obstructive CAD
0309U Cardiology (cardiovascular disease), analysis of 4 proteins (NT-proBNP, osteopontin, tissue inhibitor of metalloproteinase-1 [TIMP-1], and kidney injury molecule-1 [KIM-1]), plasma, algorithm reported as a risk score for major adverse cardiac event
0541U Cardiovascular disease (HDL reverse cholesterol transport), cholesterol efflux capacity, LC-MS/MS, quantitative measurement of 5 distinct HDL-bound apolipoproteins (apolipoproteins A1, C1, C2, C3, and C4), serum, algorithm reported as prediction of coronary artery disease (pCAD) score
81400* Molecular pathology procedure, Level 1 (eg, identification of single germline variant [eg, SNP] by techniques such as restriction enzyme digestion or melt curve analysis) *(*when billed for evaluation of angiotensin gene)*

81479* Unlisted molecular pathology procedure – when billed for any test not described as covered. *(*Explanatory notes must accompany claim)*
82777 Galectin-3
83006 Growth stimulation expressed gene 2 (ST2, Interleukin 1 receptor like-1)

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the Priority Health Provider Manual.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

- **HMO/EPO**: This policy applies to insured HMO/EPO plans.
- **POS**: This policy applies to insured POS plans.
- **PPO**: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO**: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL**: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE**: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN**: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IX. REFERENCES

Guidelines/Positions Statements

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