

## Kaiser Foundation Health Plan of Washington

# Clinical Review Criteria Cardiovascular Risk Panel

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#### Criteria

#### For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Biomarkers in Cardiovascular Risk Assessment (L36362)
Local Coverage Article	Billing and Coding: MoIDX: Biomarkers in Cardiovascular Risk
	Assessment (A57055)

#### For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that Cardiovascular Risk Panels provide better long-term outcomes than current standard services/therapies.

Cardiovascular risk panels, consisting of multiple individual biomarkers intended to assess cardiac risk (other than simple lipid panels\*) are considered **not medically necessary**. Some examples of commercially available cardiovascular risk panels include but are not limited to the following:

- Applied Genetics Cardiac Panel
- Atherotech® Diagnostics Lab CVD Risk Panel and VAP Lipid Panel
- Berkeley Heart Lab (a Quest Diagnostics service) Cardio IQ® Lipid Panel
- Health Diagnostics Cardiac Risk Panel
- Boston Heart Diagnostics
- Genova Diagnostics CV Health Plus Genomics Panel
- Genova Diagnostics CV Health Plus Panel
- Metametrix Cardiovascular Health Profile
- Cleveland HeartLab CVD Inflammatory Profile
- Applied Genetics Cardiac Panel
- Genetiks Genetic Diagnosis and Research Center Cardiovascular Risk Panel
- Quest Diagnostics 4myheart
- Singulex Cardiac Related Test Panels
  - Cardiac Dysfunction panel
  - Vascular Information and Dysfunction panel
  - Dyslipidemia panel
  - Cardiometabolic
- \* A simple lipid panel is generally composed of the following lipid measures:
  - Total cholesterol
  - LDL cholesterol
  - HDL 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), etc., are not considered to be components of a simple lipid profile.

#### If requesting review for these services, please send the following documentation:

Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage

### **Background**

Cardiovascular risk panels refer to different combinations of cardiac markers that are intended to evaluate risk of cardiovascular disease. There are numerous commercially available risk panels that include different combinations of lipids, noncardiac biomarkers, measures of inflammation, metabolic parameters, and/or genetic markers. Risk panels report the results of multiple individual tests, as distinguished from quantitative risk scores that combine results of multiple markers into one score. While the individual risk factors have in most cases been associated with increased risk of CV disease, it is not clear how the results of individual risk factors impact management changes, so it is also not certain how the panels will impact management decisions. Given the lack of evidence for clinical utility of any individual risk factor beyond simple lipid measures, it is unlikely that the use of CV risk panels improve outcome.

2010 American College of Cardiology Foundation (ACCF)/American Heart Association (AHA) Guideline for Assessment of Cardiovascular Risk in Asymptomatic Adults: Recommendation for Assessment of Lipoprotein Concentrations, Other Lipoprotein Parameters, and Modified Lipids: "Measurement of lipid parameters, including lipoproteins, apolipoproteins, particle size, and density, beyond standard fasting lipid profile is not recommended for cardiovascular disease risk assessment in asymptomatic adults." http://circ.ahaiournals.org/content/122/25/e584.full.pdf

### **Applicable Codes**

#### Considered Not Medically Necessary when billed as part of a Cardiovascular Risk Panel:

\*This is not an all-inclusive list.

CPT®	Description
Codes	
81225	CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *8, *17)
81229	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities
81240	F2 (prothrombin, coagulation factor II) (eg, hereditary hypercoagulability) gene analysis, 20210G>A variant
81241	F5 (coagulation factor V) (eg, hereditary hypercoagulability) gene analysis, Leiden variant
81291	MTHFR (5,10-methylenetetrahydrofolate reductase) (eg, hereditary hypercoagulability) gene analysis, common variants (eg, 677T, 1298C)
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)
81401	Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)
81479	Unlisted molecular pathology procedure (when utilized with a description of KIF6, 9p21, 4q25-AF, LPA Aspirin, LPA-Intron 25)

82163	Angiotensin II
82172	Apolipoprotein, each
82306	Vitamin D; 25 hydroxy, includes fraction(s), if performed
82652	Vitamin D; 1, 25 dihydroxy, includes fraction(s), if performed
82397	Chemiluminescent assay (Leptin)
82542	Column chromatography, includes mass spectrometry, if performed (eg, HPLC, LC, LC/MS, LC/MS-MS, GC, GC/MS-MS, GC/MS, HPLC/MS), non-drug analyte(s) not elsewhere specified, qualitative or quantitative, each specimen [not covered for cardiovascular disease risk]
82610	Cystatin C
82664	Electrophoretic technique, not otherwise classified
82725	Fatty acids, nonesterified [not covered for cardiovascular disease risk]
82777	Galectin-3 [not covered for cardiovascular disease risk]
83006	Growth stimulation expressed gene 2 (ST2, Interleukin 1 receptor like-1)
83090	Homocysteine
83520	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified [adiponectin] [leptin] [interleukin-6 (IL-6)] [tumor necrosis factor alpha (TNF-a)] [Oxidized phospholipids] [interleukin 17] [toll-like receptor 4 (TLR4)]
83525	Insulin, total [not covered for cardiovascular disease risk]
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 (e.g., electrophoresis, ultracentrifugation)
83704	Lipoprotein, blood; quantitation of lipoprotein particle number(s) (eg, by nuclear magnetic resonance spectroscopy), includes lipoprotein particle subclass(es), when performed
83719	Lipoprotein, direct measurement; VLDL cholesterol
83876	Myeloperoxidase (MPO)
83880	Natriuretic peptide
85384	Fibrinogen; activity
85385	Fibrinogen; antigen

\*Note: Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

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Date Created	Date Reviewed	Date Last Revised
01/25/2017	02/07/2017 <sup>MPC</sup> , 06/02/2020 <sup>MPC</sup> , 06/01/2021 <sup>MPC</sup> , 06/07/2022 <sup>MPC</sup> , 06/06/2023 <sup>MPC</sup>	12/09/2022

MPC Medical Policy Committee

Revision History	Description
02/07/2017	MPC approved to adopt criteria to manage cardiovascular risk panels that are commercially available; 60 day notice effective May 1, 2017
06/07/2018	Added LCD – L36362
06/02/2020	Added LCA Billing and Coding: MoIDX: Biomarkers in Cardiovascular Risk Assessment (A57055)
06/01/2021	Updated applicable coding – removed deleted codes 0111T and 0126T
12/09/2022	Updated applicable coding – removed deleted codes 0423T

<sup>\*\*</sup>To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.