Clinical Review Criteria
Cardiovascular Risk Panel

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Criteria
For Medicare Members

<table>
<thead>
<tr>
<th>Source</th>
<th>Policy</th>
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</thead>
<tbody>
<tr>
<td>CMS Coverage Manuals</td>
<td>None</td>
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<tr>
<td>National Coverage Determinations (NCD)</td>
<td>None</td>
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<tr>
<td>Local Coverage Determinations (LCD)</td>
<td>None</td>
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<tr>
<td>Local Coverage Article</td>
<td>Biomarkers in Cardiovascular Risk Assessment (L36362)</td>
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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

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• 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.

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

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.ahajournals.org/content/122/25/e584.full.pdf

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<tr>
<th>Date Created</th>
<th>Date Reviewed</th>
<th>Date Last Revised</th>
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<tbody>
<tr>
<td>01/25/2017</td>
<td>02/07/2017MPC</td>
<td>02/07/2017</td>
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MPC Medical Policy Committee

<table>
<thead>
<tr>
<th>Revision History</th>
<th>Description</th>
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<tbody>
<tr>
<td>02/07/2017</td>
<td>MPC approved to adopt criteria to manage cardiovascular risk panels that are commercially available; 60 day notice effective May 1, 2017</td>
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<tr>
<td>06/07/2018</td>
<td>Added LCD – L36362</td>
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Codes
The following is a list of codes that will not be covered when billed on a Cardiovascular Risk Panel. This is not an all-inclusive list.

0111T Long-chain (C20-22) omega-3 fatty acids in red blood cell (RBC) membranes
0126T Common carotid intima-media thickness (IMT) study for evaluation of atherosclerotic burden or coronary heart disease risk factor assessment
0423T Secretory type II phospholipase A2 (sPLA2-IIA)
81229 Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities [not covered for cardiovascular disease risk]
81240 Prothrombin coagulation factor II
81241 Factor V Leiden
81225 CYP2C19
81291 MTHFR
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)
82172 Apolipoprotein, each
82163 - Angiotensin II
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) enzyme immunoassay
83698 Lipoprotein-associated phospholipase A2 (Lp-PLA2)•83700 Lipoprotein, blood; electrophoretic separation
    and quantitation
83701 high resolution fractionation and quantitation of lipoprotein subclasses when performed (e.g.,
    electrophoresis, ultracentrifugation)
83704 quantitation of lipoprotein particle numbers and lipoprotein particle subclasses (e.g., by nuclear magnetic
    resonance spectroscopy)
83719 - Lipoprotein, direct measurement; VLDL cholesterol
83876 Myeloperoxidase (MPO)
83880 Natriuretic peptid
85384 Fibrinogen activity
85385 Fibrinogen antigen