

# November 2023



## Client Communication

# Medicare Local Coverage Determination Policy: CGS

## Coverage Policy

### L36139 - MoIDX: Biomarkers in Cardiovascular Risk Assessment

CPT: 81439, 82172, 82610, 83090, 83695, 83698, 83700, 83701, 83704, 83719, 83721, 86141

Revision Effective Date: 03/02/2023

### Coverage Indications, Limitations, and/or Medical Necessity

#### Indications and Limitations

Under preventative services, Medicare Part B covers the basic lipid panel (total cholesterol, high density lipoprotein-cholesterol (HDL-C), triglycerides, and low density lipoprotein-cholesterol (LDL-C)) for cardiovascular (CV) disease screening, every 5 years when ordered by a doctor.

NCD 190.23 covers **lipid panel** testing for symptomatic patients for evaluating atherosclerotic CV disease, to monitor the progress of patients on anti-lipid dietary management and pharmacologic therapy for various lipid disorders. Per NCD 190.23, "Routine screening and prophylactic testing for lipid disorders are not covered by Medicare. While lipid screening may be medically appropriate, Medicare by statute does not pay for it. Lipid testing in asymptomatic individuals is considered to be screening regardless of the presence of other risk factors such as family history, tobacco use, etc."

This policy denies coverage for **all CV risk assessment panels**, except the basic lipid panel, for symptomatic (with signs and symptoms) patients with suspected or documented CV disease because panel testing is not specific to a given patient's lipid abnormality or disease. The policy indicates the medical indication(s) based on published scientific articles and consensus guidelines for individual lipid biomarkers that may be covered to characterize a given lipid abnormality or disease, to determine a treatment plan or to assist with intensification of therapy. Each individual lipid biomarkers must be specifically ordered and the reason for the test order documented in the patient's medical record. The policy denies coverage for all **non-lipid** biomarkers when used for CV risk assessment including but not limited to, biochemical, immunologic, and hematologic, and genetic biomarkers for CV risk assessment regardless of whether ordered in a panel or individually.

The following biomarkers, when they are included in a CV risk assessment panel, are non-covered:

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- Lipoprotein subclasses;
- LDL particles;
- Intermediate density lipoproteins;
- High density lipoprotein AI9LpAI and AI/All;
- Lipoprotein(a);
- Apolipoprotein B (Apo B), apo A-I and apo E;
- Lipoprotein-associated phospholipase A2 (Lp-PLA2)
- BNP
- Cystatin C
- Thrombogenic/hematologic actors
- Interleukin-6 (IL-6), tissue necrosis factor-  $\alpha$  (TNF-  $\alpha$ ), plasminogen activator inhibitor-1 (PAI-1) and IL-6 promoter polymorphism
- Free fatty acids
- Visfatin, angiotensin-converting enzyme 1 (ACE2) and serum amyloid A
- Microalbumin
- Myeloperoxidase (MPO)
- Homocysteine and methylenetetrahydrofolate reductase (MTHFR) mutation testing
- Uric acid
- Vitamin D
- White blood cell count
- Long-chain omega-3 fatty acids in red blood cell membranes
- Gamma-glutamyltransferase (GGT)
- Genomic profiling including CardiaRisk angiotensin gene
- Leptin, ghrelin, adiponectin and adipokines including retinol binding protein 4 (RBP4) and resistin

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- Inflammatory markers including VCAM-1, P-selectin (PSEL) and E-selectin (ESEL)
- Cardiovascular risk panels

Note #1: There is no Medicare benefit for screening CV risk assessment testing for asymptomatic (without signs or symptoms of disease) patients. Screening asymptomatic patients for cardiovascular risk is statutorily excluded by Medicare and will not be addressed in this policy.

Note #2: FDA approval/clearance means that a test/assay has analytical and clinical validity. The FDA does not review clinical utility (that the test/assay demonstrates improved patient outcomes). To meet Medicare's "reasonable and necessary" criteria for coverage, a test/assay must have proven clinical utility.

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The ICD10 codes listed below are the top 40 diagnosis codes Sonic most commonly receives from ordering physicians for this limited-coverage test. Medicare supports provider utilization of all the diagnosis codes listed below, except those notated in bold. **If you are providing a diagnosis code that is bolded below, please submit a valid ABN form with the order.** To view the complete policy and the full list of medically supported diagnosis codes, please refer to the CMS website for guidance:

<https://www.cms.gov/medicare-coverage-database/search.aspx>

Codes	Description
I10	Essential (primary) hypertension
<b>E55.9</b>	<b>Vitamin D deficiency, unspecified</b>
E78.2	Mixed hyperlipidemia
<b>R53.83</b>	<b>Other Fatigue</b>
E78.5	Hyperlipidemia, unspecified
<b>R73.09</b>	<b>Other abnormal glucose</b>
E72.11	Homocystinuria
<b>E11.9</b>	<b>Type 2 Diabetes Mellitus without complications</b>
<b>R79.82</b>	<b>Elevated C-reactive protein (CRP)</b>
<b>E03.9</b>	<b>Hypothyroidism, Unspecified</b>
<b>E61.1</b>	<b>Iron deficiency</b>
<b>Z13.220</b>	<b>Encounter for screening for lipid disorders</b>
<b>Z79.899</b>	<b>Other long term (current) drug therapy</b>
<b>Z79.01</b>	<b>Long term (current) use of anticoagulants</b>
Z13.6	Encounter for screening for cardiovascular disorders
<b>R97.0</b>	<b>Elevated carcinoembryonic antigen [CEA]</b>
<b>Z13.228</b>	<b>Encounter for screening for other metabolic disorders</b>
<b>R06.02</b>	<b>Shortness of breath</b>
<b>Z79.4</b>	<b>Long term (current) use of insulin</b>
<b>E87.6</b>	<b>Hypokalemia</b>
<b>E83.42</b>	<b>Hypomagnesemia</b>
<b>Z79.02</b>	<b>Long term (current) use of anticoagulants and antithrombotics/antiplatelets</b>
<b>R97.0</b>	<b>Elevated carcinoembryonic antigen [CEA]</b>

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Z13.228	Encounter for screening for other metabolic disorders
R06.2	Wheezing
E79.0	Hyperuricaemia without signs of inflammatory arthritis and tophaceous disease
E11.65	Type 2 diabetes mellitus with hyperglycemia
D52.9	Folate deficiency anaemia, unspecified
E88.81	Metabolic syndrome and other insulin resistance
Z12.5	Encounter for screening for malignant neoplasm of prostate
E78.00	Pure hypercholesterolemia, unspecified
E29.1	Testicular hypofunction
R68.89	Other general symptoms and signs
L65.9	Nonscarring hair loss, unspecified
I25.10	Atherosclerotic heart disease of native coronary artery without angina pectoris
M62.81	Muscle weakness (generalized)
R53.81	Other malaise
E78.49	Other hyperlipidemia
E53.8	Deficiency of other specified B group vitamins
E34.9	Endocrine disorder, unspecified
D50.9	Iron deficiency anaemia, unspecified
Z13.29	Encounter for screening for other suspected endocrine disorder

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