Medica Central Coverage Policy

Policy Name:	**Lipoprotein Subclass Testing for Screening, Evaluation, and Monitoring of Cardiovascular Disease MP9681**
Effective Date:	**07/01/2025**

Important Information – Please Read Before Using This Policy
These services may or may not be covered by all Medica Central plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage.
Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers
Medica Central coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

Coverage Policy

Lipoprotein subclass testing for screening, evaluation, and monitoring of cardiovascular disease is investigative and unproven, and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the effects on health care outcomes.

Note: See also related coverage policy: *Lipoprotein-Associated Phospholipase A2 (Lp-PLA2) Immunoassay for Prediction of Risk for Coronary Heart Disease or Ischemic Stroke (PLAC® Test).*

Description

Lipoproteins are particles that transport lipids, particularly cholesterol and triglyceride, throughout the plasma. There is an association between disorders of lipoprotein metabolism and coronary heart disease, especially high serum levels of low-density lipoprotein (LDL) cholesterol and low serum levels of high-density lipoprotein (HDL) cholesterol. Tests routinely done to ascertain cardiovascular disease include measurement of plasma levels of total cholesterol, total HDL cholesterol, total LDL cholesterol, and triglycerides. It is theorized that adding evaluation of lipoprotein subclass particles could contribute to improved prediction and management of cardiovascular disease, including coronary heart disease and ischemic stroke.

Methodologies used to measure and quantify lipoprotein subclass particles include, but are not limited to:

1. Enzyme immunoassay
2. Gel tube electrophoresis
3. Gradient gel electrophoresis (GGE)
4. Lipoprotein-associated phospholipase immunoassay
5. Nuclear magnetic resonance spectroscopy assay
6. Ultracentrifugation-vertical auto profile (VAP).

Examples of lipoprotein subclass particles subject to measurement include, but are not limited to:

1. Apolipoprotein A1 (Apo A1)
2. Apolipoprotein A2 (Apo A2)
3. Apolipoprotein B (Apo B)
4. Apolipoprotein E isoforms (ApoE isoforms [E2, E3, E4])
5. HDL subparticles (e.g., LpAI, LPAI/AII, and or HDL3 and HDL2)
6. LDL subparticles (e.g., small and large LDL particles)
7. Lipoprotein remnants: intermediate density lipoproteins (IDL) and small low-density lipoproteins
8. Lipoprotein(a) [Lp(a)].

FDA Approval

Premarket approval from the FDA is required for laboratory assays marketed and distributed to clinical laboratories.

Premarket approval from the FDA is not required as long as an assay is performed in a laboratory facility that observes CLIA regulations and does not market the test for distribution.

The NMR LipoProfile® test (LipoScience, Inc., Raleigh, NC) was FDA approved for marketing in July 2008, for measurement of lipoprotein particles to quantify LDL particle number, HDL cholesterol, and triglycerides in serum and plasma.

Examples of available tests using proprietary methodologies for non-marketed tests include, but are not limited to:

1. Atherotech Diagnostics Lab (Birmingham, AL), which uses the VAP® lipid panel to provide direct measurement of standard lipids and lipoprotein subclasses.
2. Berkley HeartLab Inc. (South San Francisco, CA), which offers its LDL-S3GGE and its ApoB-Ultra to measure selected lipoprotein subclasses.
3. SpectraCell Laboratories, Inc. (Houston, TX), which uses the Lipoprotein Particle Profile™ to measure LDL-P number and subfractions.

Prior Authorization

Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes

- **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 numbers and lipoprotein particle subclasses (e.g., by nuclear magnetic resonance spectroscopy)
- **83722** – Lipoprotein, direct measurement; small dense LDL cholesterol
- **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

	Committee/Source	Date(s)
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