



Medica Central Coverage Policy

Policy Name:	Lipoprotein-associated Phospholipase A2 (Lp-PLA2) Immunoassay for Prediction of Risk for Coronary Heart Disease or Ischemic Stroke (PLAC® Test) MP9687
Effective Date:	09/01/2024

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

Note: This policy is longer scheduled for routine review of the scientific literature.

Lipoprotein-associated phospholipase A2 (Lp-PLA2) immunoassay for prediction of risk for coronary heart disease or ischemic stroke (PLAC® Test) 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 Subclass Testing for Screening, Evaluation, and Monitoring of Cardiovascular Disease*.

Description

The lipoprotein-associated phospholipase A₂ (Lp-PLA2) immunoassay, [diaDexus PLAC® test] is an enzyme immunoassay laboratory test intended for the quantitative determination of Lp-PLA2 in the patient's plasma. Lp-PLA2 is a cardiovascular-specific inflammatory enzyme associated with unstable plaque. The Lp-PLA2 enzyme works in association with low-density lipoprotein (LDL). Lp-PLA2 is transported to the walls of coronary arteries by LDL, where the enzyme can activate an inflammatory response which in turn leads to the promotion of atherosclerosis. As a result, Lp-PLA2 is purported to act as a specific indicator of vascular inflammation. The Lp-PLA2 immunoassay is based on the principle of a sandwich enzyme immunoassay using two specific monoclonal antibodies. The test uses absorbance technology to plot a standard curve against which the Lp-PLA2 concentration in a test sample can be compared and quantified using computer software evaluation.

The immunoassay test is suggested for use in conjunction with clinical evaluation and patient risk assessment as an aid in predicting risk for coronary heart disease and ischemic stroke associated with atherosclerosis. It is purported that individuals identified as being at high risk for coronary



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heart disease or stroke based on elevated Lp-PLA2 levels will initiate proactive, long-term preventive measures, such as lifestyle modification and therapeutic intervention, which might result in improved health outcome.

FDA Approval

The original PLAC® Test ELISA Kit (Diadexus) was granted FDA Pre-Market Notification marketing approval in July 2003 for predicting risk of coronary heart disease (CHD). It was subsequently granted additional marketing approval in June 2005 for prediction of risk for CHD and ischemic stroke. This test is offered through clinical reference labs and cardiovascular specialty labs.

The PLAC® Test for Lp-PLA2 Activity was granted FDA marketing approval in December 2014. The Lp-PLA2 Activity test is offered through a select number of laboratories.

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

83698 – Lipoprotein-associated phospholipase A2, (Lp-PLA2)

	Committee/Source	Date(s)
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