LIPOPROTEIN-ASSOCIATED PHOSPHOLIPASE A₂ (Lp-PLA₂) TEST (PLAC® TEST) FOR PREDICTION OF CORONARY HEART DISEASE AND ISCHEMIC STROKE
HS-081

Lipoprotein-Associated Phospholipase A₂ (Lp-PLA₂) Test (PLAC® Test) for Prediction of Coronary Heart Disease and Ischemic Stroke

Policy Number: HS-081

Original Effective Date: 2/2/2009


APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member’s particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member’s benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any. All links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change prior to the annual review date. Lines of business (LOB) are subject to change without notice; current LOBs can be found at www.wellcare.com. All guidelines can be found at this site as well but selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

"Adoption of this technology is not expected to result in an increase in outpatient facility use since blood samples for testing can be collected during other routine outpatient care. Use of the PLAC test may result in a decrease in inpatient and outpatient facility use for stroke management since the PLAC test may improve identification of patients who have increased stroke risk, which would allow initiation of preventive treatments. However, the available studies have not demonstrated conclusively that this testing improves identification of patients who have elevated stroke risk. Furthermore, the available studies have not determined whether information provided by PLAC testing can be used effectively to guide treatment and improve patient outcomes. Demand for the PLAC test may
increase if further studies indicate that this testing improves the accuracy of stroke risk prediction."

Davidson et al (2008)* released the following statement regarding Lp-PLA₂ Testing: "A consensus panel was formed to review the rapidly emerging literature on the vascular-specific inflammatory marker lipoprotein-associated phospholipase A2 (Lp-PLA₂) and to update recommendations for the appropriate use of this novel biomarker in clinical practice. The recommendations of the panel build on guidelines of the Adult Treatment Panel III (ATP III) and the American Heart Association/Centers for Disease Control (AHA/CDC) for cardiovascular risk assessment. Consistent with the ATP III guideline recommendations for the use of inflammatory markers, Lp-PLA₂ is recommended as an adjunct to traditional risk assessment in patients at moderate and high 10-year risk. A simplified framework for traditional Framingham risk factor assessment is proposed. As a highly specific biomarker for vascular inflammation, elevated Lp-PLA₂ levels should prompt consideration of increasing the cardiovascular risk category from moderate to high or high to very high risk, respectively. Because intensification of lifestyle changes and low-density lipoprotein (LDL) cholesterol lowering is beneficial in high-risk patients, regardless of baseline LDL cholesterol levels, consideration should be given to lowering the LDL cholesterol target by 30 mg/dL (1 mg/dL = 0.02586 mmol/L) in patients with high levels of Lp-PLA₂. Lp-PLA₂ is recommended as a diagnostic test for vascular inflammation to better identify patients at high or very high risk who will benefit from intensification of lipid-modifying therapies. However, at this time Lp-PLA₂ cannot be recommended as a target of therapy."

* NOTE: Authors of this consensus have received financial considerations from the manufacturer of the PLAC® Test, diaDexus Inc.

In 2008 the American Diabetes Association (ADA) and the American College of Cardiology (ACC) released a joint consensus statement on lipoprotein management in patients with cardiometabolic risk. There is no mention of Lp-PLA₂ in this document.

POSITION STATEMENT

Applicable To:
☑ Medicaid
☑ Medicare

The use of the PLAC® Test for the prediction of coronary heart disease and ischemic stroke in moderate to high risk members and as a tool for the guidance of treatment options for the aforementioned diseases is considered experimental and investigational and NOT a covered benefit.

CODING

Non-Covered CPT® Code
83698 Lipoprotein-associated phospholipase A2, (Lp-PLA₂)

ICD-10-CM Diagnosis Codes
All diagnoses for measurement of Lp-PLA₂ are considered experimental or investigational.

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES


MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

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