



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



Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

Harmony Health Plan of Illinois, Inc.

HealthEase of Florida, Inc.

'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona, Inc.

WellCare Health Insurance of Illinois, Inc.

WellCare Health Insurance of New York, Inc.

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WellCare of Texas, Inc.

WellCare Prescription Insurance, Inc.

**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

**Revised Date(s): 2/26/2010; 2/26/2011;
2/2/2012**

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. 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 Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. 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.

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.

BACKGROUND

Hayes Statement (from Hayes Brief, Technology at a Glance, July 18, 2007, Hayes Rating: D)

“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.”

Expert Consensus Statement

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.

Society Statements

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

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.**



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CODING

Non-Covered CPT®* Code

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

ICD-9-CM Procedure Code - No applicable code

HCPCS Codes - No applicable code

Non-Covered ICD-9 Diagnoses Codes

All diagnoses for measurement of Lp-PLA₂ are considered experimental or investigational.

*Current Procedural Terminology (CPT®) ©2012 American Medical Association: Chicago, IL.

REFERENCES

Peer Reviewed

1. Davidson, M.H., Corson, M.A., Alberts, M.J., Anderson, J.L., Gorelick, P.B., Jones, P.H., & et al. (2008). Consensus panel recommendation for incorporating lipoprotein-associated phospholipase A2 testing into cardiovascular disease risk assessment guidelines. *American Journal of Cardiology*, 1010, 12, S51F–57F.
2. Hayes Directory. (2007, July 18). Lipoprotein-associated phospholipase A2 (Lp-PLA2) test (PLAC® test) (diaDexus Inc.) for prediction of ischemic stroke. Retrieved from <http://www.hayesinc.com>

Government Agencies, Professional and Medical Organizations

N/A

HISTORY AND REVISIONS

Date	Action
2/2/2012	• Approved by MPC. No changes.
12/1/2011	• New template design approved by MPC.
2/26/2011	• Approved by MPC.