Medical Coverage Policy | Measurement of Small Low-Density Lipoprotein (LDL) Particles

EFFECTIVE DATE: 02|01|2005
POLICY LAST UPDATED: 02|16|2022

OVERVIEW

Lipoprotein-associated phospholipase A2 (Lp-PLA2), also known as platelet-activating factor acetylhydrolase is an enzyme that hydrolyzes phospholipids and is primarily associated with low-density lipoproteins (LDLs). Accumulating evidence has suggested that Lp-PLA2 is a biomarker of coronary artery disease (CAD) and may have a proinflammatory role in the progression of atherosclerosis.

For coverage of tests filed with PLA codes (0052U-VAP Cholesterol Test), please refer to the related policy "Proprietary Laboratory Analyses (PLA)."

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

Measurement of lipoprotein-associated phospholipase A2 (Lp-PLA2) is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

Measurement of lipoprotein-associated phospholipase A2 (Lp-PLA2) is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND

Low-density lipoproteins (LDL) have been identified as the major atherogenic lipoproteins and have long been identified by the National Cholesterol Education Project (NCEP) as the primary target of cholesterollowering therapy. LDL particles consist of a surface coat composed of phospholipids, free cholesterol, and apolipoproteins, surrounding an inner lipid core composed of cholesterol ester and triglycerides. Traditional lipid risk factors such as low-density lipoprotein-cholesterol (LDL-C), while predictive on a population basis, are weaker markers of risk on an individual basis. Only a minority of subjects with elevated LDL and cholesterol levels will develop clinical disease, and up to 50% of cases of coronary artery disease (CAD) occur in subjects with 'normal' levels of total and LDL cholesterol.

Although treatment for elevated coronary disease risk with statins targets cholesterol levels, selection for treatment involves estimation of future CAD risk using well-validated prediction models that use additional variables.

Lipoprotein-associated phospholipase A2 (Lp-PLA2), also known as platelet-activating factor acetylhydrolase, is an enzyme that hydrolyzes phospholipids and is primarily associated with LDLs. Accumulating evidence has suggested that Lp-PLA2 is a biomarker of CAD and may have a proinflammatory role in the progression of atherosclerosis. Recognition that atherosclerosis represents, in part, an inflammatory process has created considerable interest in measurement of proinflammatory factors as part of cardiovascular disease risk assessment.

Interest in Lp-PLA2 as a possibly causal risk factor for CAD has generated development and testing of Lp-PLA2 inhibitors as a new class of drugs to reduce risk of CAD. However, clinical trials of Lp-PLA2 inhibitors have not shown significant reductions in CAD end points. Furthermore, assessment of Lp-PLA2 levels has not been used in the selection or management of subjects in the clinical trials.

Regulatory Status
In December 2014, the PLAC® Test (diaDexus), a quantitative enzyme assay, was cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process for Lp-PLA2 activity. It was considered substantially equivalent to a previous version of the PLAC® Test (diaDexus), which was cleared for marketing by the Food and Drug Administration in July 2003.

For individuals who have a risk of cardiovascular disease who receive Lp-PLA2 testing, the evidence includes studies of the association between Lp-PLA2 and various coronary artery disease outcomes. Relevant outcomes are overall survival, disease-specific survival, and test validity. The studies have demonstrated that Lp-PLA2 levels are an independent predictor of cardiovascular disease. Although Lp-PLA2 levels are associated with cardiovascular disease risk, changes in patient management that would occur as a result of obtaining Lp-PLA2 levels in practice are not well-defined. To demonstrate clinical utility, clinicians must have the tools to incorporate Lp-PLA2 test results into existing risk prediction models that improve classification into risk categories alter treatment decisions and lead to improved health outcomes. Direct evidence for such improved health outcomes with Lp-PLA2 testing in clinical practice is lacking. The evidence is insufficient to determine the effects of the technology on health outcomes. Therefore, this service is not covered for BlueCHiP for Medicare and not medically necessary for Commercial products.

CODING
The following code is not covered for Medicare Advantage Plans and not medically necessary for Commercial products:
83698 Lipoprotein-associated phospholipase A_2, (Lp-PLA_2)

RELATED POLICIES
Proprietary Laboratory Analyses (PLA)

PUBLISHED
Provider Update, April 2022
Provider Update, March 2021
Provider Update, March 2020
Provider Update, September 2019
Provider Update, Nov. /Dec. 2018
Provider Update, November 2017
Provider Update, January 2017
Provider Update, October 2015
Provider Update, January 2014

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