OVERVIEW
Lipoprotein-associated phospholipase A2 (Lp-PLA2), 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.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHIP for Medicare and 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/contracts. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for services not medically necessary.

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 cholesterol-lowering 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.

For individuals who have a risk of cardiovascular disease (CVD) who receive lipoprotein-associated phospholipase A2 (Lp-PLA2) testing, the evidence includes studies of analytic validity and 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 CVD. Evidence of clinical utility is lacking. To improve outcomes, clinicians must have the tools to incorporate Lp-PLA2 test results into existing risk prediction models, and these models should demonstrate improved classification into risk categories that will improve treatment and health outcomes. Direct evidence for improved health outcomes with the use of Lp-PLA2 in clinical practice is lacking. Although Lp-PLA2 levels are associated with CVD risk, changes in patient management that would occur as a result of obtaining Lp-PLA2 levels in practice are not well-defined. The evidence is insufficient to determine the effects of the technology on health outcomes. Therefore, this service is not medically necessary for BlueCHiP for Medicare and Commercial products.

CODING
BlueCHiP for Medicare and Commercial Products
The following code is considered not medically necessary:
83698

RELATED POLICIES
Novel Biomarkers in Risk Assessment and Management of Cardiovascular Disease

PUBLISHED
Provider Update, November 2017
Provider Update, January 2017
Provider Update, October 2015
Provider Update, January 2014
Provider Update, December 2011
Provider Update, January 2011
Provider Update, August 2009
Provider Update, November 2008

REFERENCES


