

Cardiovascular Disease Risk Assessment and Management Using Novel Biomarkers

I. Policy

Numerous nontraditional lipid and other biomarker measurements have been proposed for use in improving risk prediction for cardiovascular disease. These biomarkers have been studied as an alternative or addition to standard lipid panels for risk stratification in CVD or as treatment targets for lipid-lowering therapy. There is no high-quality evidence that use of these markers leads to health outcome improvements when used in place of traditional lipid targets such as LDL. Because of the deficiencies in the literature around these issues, the use of these novel lipid risk markers does not meet the criteria for medical necessity.

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. 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. Because current evidence is insufficient to determine the effects of the technology on health outcomes, Lp-PLA2 for CAD risk assessment does not meet the criteria for medical necessity.

University Health Alliance (UHA) does not reimburse for the biomarkers listed below in risk assessment and routine management of cardiovascular disease. Moreover, other biomarkers with plausible but unproven general utility are, similarly, not covered.

II. Criteria/Guidelines

- A. Measurement of the following novel lipid and non-lipid risk factors are **not** covered in the risk assessment and routine management of cardiovascular disease (Note: this list of non-covered testing is not all-inclusive and other biomarkers with unproven general utility are similarly non-covered):
1. Apolipoprotein B
 2. Apolipoprotein A-1
 3. Apolipoprotein E
 4. B-type natriuretic peptide
 5. Cystatin C
 6. Fibrinogen
 7. High-density lipoprotein (HDL) subclass
 8. Leptin
 9. Low-density lipoprotein (LDL) subclass
 10. Lipoprotein A
 11. Lipoprotein-associated phospholipase A2 (Lp-PLA2)
- B. The provider should not bill or collect charges for these services unless a written acknowledgement of financial responsibility, specific to the service, is obtained from the Member prior to the time services are rendered.

NOTE:

This UHA payment policy is a guide to coverage, the need for prior authorization and other administrative directives. It is not meant to provide instruction in the practice of medicine, and it should not deter a provider from expressing his/her judgment.

Even though this payment policy may indicate that a particular service or supply is considered covered, specific provider contract terms and/or members' individual benefit plans may apply, and this policy is not a guarantee of payment. UHA reserves the right to apply this payment policy to all UHA companies and subsidiaries.

UHA understands that opinions about and approaches to clinical problems may vary. Questions concerning medical necessity (see Hawaii Revised Statutes §432E-1.4) are welcome. A provider may request that UHA reconsider the application of the medical necessity criteria in light of any supporting documentation.

III. Policy History

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