The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is not required but is recommended if, despite the position of this Protocol, you feel this service is medically necessary. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

Description

Lipoprotein(a) (LPA) is a lipid-rich particle similar to low-density lipoprotein (LDL) and has been determined to be an independent risk factor for coronary artery disease (CAD). Patients with a positive test for the LPA genetic variant, rs3798220, have a higher risk for thrombosis and therefore may derive greater benefit from the antithrombotic properties of aspirin. As a result, testing for the rs3798220 variant has been proposed as a method of stratifying benefit from aspirin treatment.

Background

Much epidemiologic evidence has determined that LPA blood level is an independent risk factor for cardiovascular disease. The overall risk associated with LPA appears to be modest, and the degree of risk may be mediated by other factors such as LDL levels and/or hormonal status.

LPA levels are relatively stable in people over time but vary up to 1000-fold between people, presumably on a genetic basis. A single nucleotide polymorphism (SNP) in the LPA gene, LPA rs3798220, has been associated with both elevated LPA levels and an increased risk of cardiovascular disease. This polymorphism substitutes methionine for isoleucine at amino acid position 4399 and is also called I4399M. Mendelian randomization studies have supported the hypothesis that this genetic variant, and the subsequent increase in LPA levels, are causative of cardiovascular disease.

Aspirin is a well-established treatment for patients with known CAD. It also is prescribed as primary prevention for some patients who are at increased risk of CAD. Current recommendations for primary prevention consider the future risk of cardiovascular events weighed against the bleeding risk of aspirin. U.S. Preventive Services Task Force guidelines from 2009 recommend aspirin for men between the ages of 45 and 79 years when the benefit in reducing myocardial infarction (MI) exceeds the risk of bleeding, particularly gastrointestinal hemorrhage; and for women between the ages of 55 and 79 years when the benefit in reducing stroke exceeds the risk of gastrointestinal bleeding. Given guidelines such as these that recommend individualizing the risk/benefit ratio of aspirin therapy, additional tools that would aid in better defining the benefits of aspirin, and/or the risk of bleeding, have potential utility for clinicians who are making decisions about aspirin therapy.

LPA-Aspirin Check® is a commercially available genetic test (Berkeley HeartLab) that detects the presence of the rs3798220 allele. Patients with a positive test for rs3798220 have a higher risk for thrombosis and therefore may derive more benefit from the antithrombotic properties of aspirin. It has been proposed that the additional information obtained from the LPA-Aspirin Check® test may aid physicians in better estimating the benefit/risk of aspirin therapy and therefore may aid in deciding whether to prescribe aspirin for individual patients.
FDA Status

The LPA-Aspirin Check® test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). Thus, genotyping is offered as a laboratory-developed test. Clinical laboratories may develop and validate tests in-house (“home-brew”) and market them as a laboratory service; such tests must meet general regulatory standards of the Clinical Laboratory Improvement Act (CLIA). The laboratory offering the service must be licensed by CLIA for high-complexity testing. Berkeley HeartLab is a CLIA-certified laboratory.

Policy (Formerly Corporate Medical Guideline)

The use of genetic testing for the rs3798220 allele (LPA-Aspirin Check®) is considered Investigational in patients who are being considered for treatment with aspirin to reduce risk of cardiovascular events.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). C-Reactive Protein as a Cardiac Risk Marker (Special Report). TEC Assessments 2002; Volume 17, Tab 23.


