Medical Policy
Genetic Testing for Lipoprotein(a) Variant(s) as a Decision Aid for Aspirin Treatment

Table of Contents
- Policy: Commercial
- Policy: Medicare
- Authorization Information
- Coding Information
- Description
- Policy History
- Information Pertaining to All Policies
- References

Policy Number: 339
BCBSA Reference Number: 2.04.70

Related Policies
- Gene Expression Testing to Predict Coronary Artery Disease, #349
- Genotyping for 9p21 Single Nucleotide Polymorphisms to Predict Risk of Cardiovascular Disease or Aneurysm, #340
- Homocysteine Testing in the Screening, Diagnosis, and Management of Cardiovascular Disease, #016
- KIF6 Genotyping for Predicting Cardiovascular Risk and or Effectiveness of Statin Therapy, #129
- Measurement of Lipoprotein-Associated Phospholipase A2 (Lp-PLA2) in the Assessment of Cardiovascular Risk, #558
- Novel Lipid Risk Factors in Risk Assessment and Management of Cardiovascular Disease, #283

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

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

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Commercial Managed Care (HMO and POS)</th>
<th>This is not a covered service.</th>
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<tr>
<td>Commercial PPO and Indemnity</td>
<td>This is not a covered service.</td>
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CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes
There is no specific CPT code for this test.

ICD-9 Diagnosis Codes
Investigational for all diagnoses.

Description
Lipoprotein(a) (LPA) is a lipid-rich particle similar to low-density lipoprotein (LDL). Epidemiologic evidence has determined that an LPA blood level is a modest independent risk factor for cardiovascular disease however; it may be mediated by serum LDL levels or hormonal status. Levels of LPA are relatively stable in individuals over time but vary up to 1,000-fold between individuals, presumably on a genetic basis. A single nucleotide polymorphism (LPA rs3798220) has been identified in the LPA gene that has been associated with both elevated levels of Lipoprotein(a) and an increased risk of cardiovascular disease. It is hypothesized that patients with a positive test for rs3798220 have a higher risk for thrombosis and thus adverse cardiovascular events which could be mitigated with daily low dose aspirin therapy.

Aspirin is a well-established treatment for patients with known coronary artery disease (CAD) or increased risk for CAD to prevent arterial and venous thrombosis. However, in recent studies published in 2012, aspirin therapy was not associated with a reduction in deaths due to heart attack and stroke, but it was associated with a significant increase in risk for bleeding.

An example of a genetic test for LPA as a decision aid for aspirin treatment is Aspirin Check® from Berkeley HeartLabs. All genetic tests for LPA to test for the presence of rs3798220 allele are considered investigational regardless of the commercial name, the manufacturer, or FDA approval status.

Summary
Testing for the LPA minor allele rs378220 is commercially available, but the performance characteristics are uncertain and standardization of testing has not been demonstrated. Several observational studies have established that this genetic variant is an independent risk factor for cardiovascular disease.

Evidence from a post-hoc analysis of the Women’s Health Study reported that carriers of the allele may derive greater benefit from aspirin treatment compared to noncarriers. It is unclear whether this information derived from genetic testing leads to changes in management. In particular, it cannot be determined from the available evidence whether deviating from current guidelines on treatment with ASA based on LPA genetic testing improves outcomes. Therefore, measurement of the LPA rs3798220 variant as a decision aid for aspirin treatment is considered investigational.

Policy History

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<tr>
<th>Date</th>
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<tr>
<td>9/2014</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>6/2013</td>
<td>New references from BCBSA National medical policy.</td>
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<td></td>
<td>No changes to policy statements.</td>
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New policy, effective 1/1/2012, describing ongoing non-coverage.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

References

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). C-Reactive Protein as a Cardiac Risk Marker (Special Report). TEC Assessments 2002; Volume17, Tab 23.