BlueCross BlueShield of North Carolina

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Corporate Medical Policy

Genotyping for 9p21 Genetic Polymorphisms to Predict Cardiovascular Disease Risk

File Name:	genotyping_for_9p21_genetic_polymorphisms_to_predict_cardiovascular_disease_risk
Origination:	7/2011
Last CAP Review:	10/2011
Next CAP Review:	10/2012
Last Review:	10/2011

Description of Procedure or Service

A number of highly correlated single nucleotide polymorphisms (SNPs) found in the chromosome 9 region p21 locus (9p21) have been significantly associated with myocardial infarction (MI), particularly early onset MI, and other manifestations of cardiovascular disease (CVD). Associations with abdominal aortic aneurysm and with intracranial aneurysm have also been reported. Genotyping for 9p21 SNPs may be offered as an approach to identify patients who may be at increased risk of some of these outcomes.

The Berkeley HeartLab offers the 9p21-EarlyMICheck™ Genotype Test, which detects the rs10757278 A>G and rs1333049 G>C SNPs within the 9p21 locus of chromosome. It is suggested that the test may help identify patients at increased risk for early onset myocardial infarction, for abdominal aortic aneurysm, and for myocardial infarction / coronary heart disease in general, allowing providers to characterize and reduce other contributing risk factors.

Cardiac risk genotyping panels offered by other laboratories may include and individually report 9p21 SNP results. For example, the deCODE MI™ test genotypes 9p21.3 rs10757278 in addition to 7 other SNPs from other chromosomal loci to estimate the risk of coronary heart disease and MI.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

Genotyping for 9p21 Genetic Polymorphisms to Predict Cardiovascular Disease Risk is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Genotyping for 9p21 Genetic Polymorphisms is covered

Not applicable

Genotyping for 9p21 Genetic Polymorphisms to Predict Cardiovascular Disease Risk

When Genotyping for 9p21 Genetic Polymorphisms is not covered

Genotyping for 9p21 single nucleotide polymorphisms is considered investigational, including use to identify patients who may be at increased risk of cardiovascular disease or its manifestations (e.g., MI, ischemic stroke) or those who may be at increased risk of abdominal aortic aneurysm or intracranial aneurysm.

Policy Guidelines

The association of 9p21 SNP alleles with CHD/CAD outcomes (clinical validity) is well-established and consistent in multiple independent populations, with evidence of increasing severity of outcomes with increasing risk allele dosage. The clinical validity for 9p21 and ischemic stroke or abdominal aortic aneurysm is less well-studied and less certain. Despite the clinical validity evidence for CHD/CAD outcomes, however, clinical utility, i.e. that the use of the test to change medical management improves CHD/CAD health outcomes, is not established. No studies have shown that 9p21 genotyping significantly improves risk reclassification after initial classification by traditional risk factors, nor have studies shown that addition of 9p21 genotyping to traditional risk factors improves risk assessment, an intermediate outcome.

There is no manufactured test kit for 9p21 genotyping that has been reviewed by the Food and Drug Administration. 9p21 genotyping tests are laboratory-developed tests (LDTs) offered by clinical laboratories licensed under CLIA for high-complexity testing.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: There is no specific CPT code for this test. A series of molecular diagnostic codes such as 83891, 83892, 83896, 83898, 83903, 83912 or an unlisted code such as 84999 (unlisted chemistry procedure) would likely be used.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.71, 5/12/11

Palomaki GE, Melillo S, Bradley LA. Association between 9p21 genomic markers and heart disease: a meta-analysis. JAMA 2010; 303(7):648-56.Retrieved on May 23, 2011 from http://jama.ama-assn.org/content/303/7/648.full

Teutsch SM, Bradley LA, Palomaki GE et al. The Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Initiative: methods of the EGAPP Working Group. Genet Med 2009; 11(1):3-

14.Retrieved on May 23, 2011 from http://journals.lww.com/geneticsinmedicine/Fulltext/2010/12000/Recommendations_from_the_EGAPP_Working_Group_.11.aspx

Medical Director review 7/2011

Specialty Matched Consultant Advisory Panel review 10/2011

Policy Implementation/Update Information

7/19/11 New policy implemented. Genotyping for 9p21 single nucleotide polymorphisms is considered investigational, including use to identify patients who may be at increased risk of cardiovascular disease or its manifestations (e.g., MI, ischemic stroke) or those who may be at increased risk of abdominal aortic aneurysm or intracranial aneurysm. Medical Director review 7/2011. (mco)

11/8/11 Specialty Matched Consultant Advisory Panel review 10/2011. No changes to Policy Statement. (mco)