Homocysteine Testing in the Screening, Diagnosis, and Management of Cardiovascular Disease

Medical Benefit

Effective Date: 10/01/12
Next Review Date: 07/15

Preauthorization

No
Review Dates: 09/09, 09/10, 07/11, 07/12, 07/13, 07/14

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 this Protocol position, 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

Homocysteine is an amino acid found in the blood; levels are inversely correlated with folate levels. Homocysteine has been evaluated as a potential marker of cardiovascular disease (CVD) in the general population and as a potential risk marker among people with CVD. The association between homocysteine-lowering interventions and risk of CVD has also been examined.

Background

Homocysteine is a sulfur-containing amino acid that is rapidly oxidized in plasma into homocysteine and cysteine-homocysteine disulfide. Measurement of total plasma homocysteine is the sum of homocysteine and its oxidized forms. The laboratory test is referred to as either homocysteine or homocyst(e)ine.

Plasma levels of homocysteine have been actively researched as a risk factor for CVD, initially based on the observation that patients with hereditary homocystinuria, an inborn error of metabolism associated with high plasma levels of homocysteine, had a markedly increased risk of CVD. Subsequently, prospective epidemiologic studies were conducted to determine if an elevated plasma level of homocysteine was an independent risk factor for CVD and could be used to improve current risk prediction models.

Interest in homocysteine as a potentially modifiable risk factor has been stimulated by the epidemiologic finding that levels of homocysteine are inversely correlated with levels of folate. This finding has raised the possibility that treatment with folic acid might lower homocysteine levels and, in turn, reduce the risk of CVD. Therefore, homocysteine has potential utility both as a risk predictor and as a target of treatment.

Determination of homocysteine concentration may be offered as a component of a comprehensive cardiovascular risk assessment that may include evaluation of small-density lipoproteins, subclassification of high-density lipoproteins, evaluation of lipoprotein (A), high-sensitivity C-reactive protein, and genotyping of apolipoprotein E.

Regulatory Status

Several homocysteine test systems have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. These include the liquid-stable two-part homocysteine reagent test by Catch Inc. (Maple Valley, WA) in 2006. Catch Inc. was purchased by Axis-Shield (Scotland) in 2010 and the Catch branded products were phased out in 2011. The test is indicated for the in vitro quantitative determination of total homocysteine in serum and plasma to assist in diagnosing and treating patients with suspicion of homocystinuria and hyperhomocysteinemia. Other homocysteine test systems cleared for marketing by FDA

**Related Protocol**

Novel Biomarkers in Risk Assessment and Management of Cardiovascular Disease

**Policy (Formerly Corporate Medical Guideline)**

Measurement of plasma levels of homocysteine is considered **investigational** in the screening, evaluation, and management of patients for cardiovascular disease.

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; 17 Tab 23.
8. Park CS, Ihm SH, Yoo KD et al. Relation between C-reactive protein, homocysteine levels, fibrinogen and lipoprotein levels and leuokocyte and platelet counts, and 10-year risk for cardiovascular disease among healthy adults in the USA. Am J Cardiol 2010; 105(9):1284-88.


