BlueCross BlueShield of Alabama

Name of Policy:
B-Natriuretic Peptide

Policy #: 142
Category: Laboratory

Latest Review Date: September 2011
Policy Grade: **Active Policy but no longer scheduled for regular literature reviews and updates.**

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

Brain natriuretic peptide (BNP) is a 32-amino acid polypeptide and is classed a cardiac neurohormone that is secreted by the ventricles of the heart in response to volume expansion and pressure overload. The peptide was first isolated from a porcine brain in 1988 and later from the cardiac ventricles of porcine, rat and humans. There are three major natriuretic peptides; atrial natriuretic peptide (ANP), BNP, and C-type natriuretic peptide (CNP) with BNP showing the most promise for diagnostic and prognostic marker of cardiac dysfunction.

BNP release appears to be in direct response to ventricular volume stretch and pressure overload. The most widely investigated use for BNP has been in heart failure (HF). Measurement of BNP is a highly sensitive and moderately specific method of differentiating heart failure from other non-cardiac causes of dyspnea. Blood levels of BNP are elevated in heart failure.
Early testing measures for BNP was via radioimmunoassay and results could take several hours. Biosite has the only FDA approved point of care testing (Triage ® BNP Test) for use in the diagnosis and assessment of chronic heart failure and for the risk stratifications of acute coronary syndromes. This test can provide results in 15 minutes. The normal values vary among labs and methods used: Normal 0-99 picograms per milliliter (pg/mL). Lab values of 80-100 pg/mL indicate possible heart failure and 100 pg/mL or greater indicates heart failure.

Policy:

B-natriuretic peptide does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage when used **for routine screening** and is considered **investigational**.

Effective for dates of service on of after December 16, 2005:
B-natriuretic peptide meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage in the urgent care setting, in the outpatient setting or in the physician's office for the diagnosis and treatment of congestive heart failure or when performed in the first few days following an acute coronary event for risk stratification.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

Congestive heart failure (CHF) is the fourth leading cause of adult hospitalizations in the United States and affects five million Americans with 500,000 new cases each year (Maisel, 2002). 800,000 are hospitalized each year with 300,000 deaths. For patients over the age of 65, congestive heart failure is the leading cause of hospitalization and accounts for 3% to 5% of the health care budget.

Maisel et al published the results of the Breathing Not Properly Multinational Study in the New England Journal of Medicine, July 18, 2002. In this study, 1586 emergency department patients with acute dyspnea had BNP levels drawn at bedside and received complete evaluation by the emergency department physician. Two independent cardiologists that examined all clinical information except the BNP levels verified the diagnosis of CHF. BNP levels were more accurate for diagnosing HF at 83.4%, negative predictive value was 96%. The conclusion was that when combined with other clinical information, rapid BNP levels are more useful in establishing or excluding the diagnosis of CHF in patients with acute dyspnea.

The 2001 American Heart Association/American College of Cardiology Guidelines for the Evaluation and Management of Chronic Heart Failure in the Adult stated: "A plasma BNP level grater than 100pg/mL supports a diagnosis of abnormal ventricular function or symptomatic HF. Clinical experience with this diagnostic marker is very limited, but it may have utility in the urgent-care setting, where it has been used to differentiate dyspnea due to HF from pulmonary disease with acceptable sensitivity and specificity. It may also be useful in managing patients with HF, but more research will be necessary to determine its role in both diagnosis and management".

BNP is a neurohormone synthesized predominantly in ventricular myocardium and is released into circulation in response to ventricular dilatation and pressure overload. Plasma levels of BNP elevates in patients with congestive heart failure and increases in proportion to the degree of left ventricular dysfunction and the severity of symptoms of heart failure. DeLemos et al measured plasma BNP levels in over 2500 patients from 40 ± 20 hours after the onset of ischemic symptoms. The plasma levels correlated with the risk of death, heart failure, and myocardial infarction at 30 days and 10 months. The base line outcomes were higher among patients who died than among those who were alive at 30 days. They concluded that a single measurement of BNP obtained in the first few days after the onset of ischemic symptoms, provides predictive information for use in risk stratification across the spectrum of acute coronary syndromes. This suggests that BNP should be measured after an acute coronary syndrome in order to identify patients at high and low risk for adverse outcomes and that treatment should be adjusted accordingly.

January 2007 Update
There is no new information available that would alter the coverage statement on this policy.

January 2009 Update
In the ACC/AHA 2005 Chronic Heart Failure Guideline Update, BNP is included in the section on Initial and Serial Clinical Assessment of Patients Presenting with Heart Failure. Under Class IIa (with level of evidence: A), the guidelines state "that measurement of B-type natriuretic peptide can be useful in the evaluation of patients presenting in the urgent care setting in whom the clinical diagnosis of HF is uncertain". Trials with this marker this diagnostic marker suggest utility in the urgent-care setting, where it has been used in combination with clinical evaluation to differentiate dyspnea due to HF from dyspnea of other causes, and suggest that its use may reduce the time to hospital discharge and the cost of treatment.

The recommendation under for serial clinical assessment of patients presenting with HF is Class IIb (level of evidence: C). The guideline states regarding "serial measurements of BNP to guide therapy for patients is not well established". Serial BNP levels have been shown to parallel the clinical severity of HF as assessed by NYHA class in broad populations. Levels are higher in hospitalized and tend to decrease during aggressive therapy for decompensation. However, it cannot be assumed that BNP levels can be used effectively as targets for adjustment of therapy individual patients. Ongoing trials will help to determine the role of serial BNP measurements in both diagnosis and management of BNP.

2011 Update
In 2009, the American College of Cardiology (ACC) and the American Heart Association (AHA) published a focused update of the *ACC/AHA 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult*. The guidelines writing committee reviewed recent trial data and other clinical information in the revision process for the 2009 update.

Updates to the section on the evaluation of patients presenting with heart failure were made to clarify the role of functional assessment beyond the New York Heart Association (NYHA) classification, and to expand on the use of brain natriuretic peptide (BNP) and N-terminal prohormone brain natriuretic peptide (NT-proBNP) testing for patient evaluation. According to the update, patients with left ventricular dysfunction or heart failure generally present in one of three ways: with a syndrome of decreased exercise tolerance; with a syndrome of fluid retention; or with no symptoms, or symptoms of another cardiac or noncardiac disorder.

The 2009 updated recommendation stated the following:
Measurement of natriuretic peptides (i.e., BNP and NT-proBNP) can be useful in the evaluation of patients presenting in the urgent care setting in whom the clinical diagnosis of heart failure is uncertain. Measurement of natriuretic peptides can be useful in risk stratification. (Level of Evidence: A) The 2005 guidelines also recommended measurement of BNP for evaluating patients who present in the urgent care setting with possible heart failure; the 2009 update expanded this recommendation to include the measurement of NT-proBNP. The level of evidence remained the same for this recommendation. The 2009 update warns that, although elevated natriuretic peptide levels may help confirm a suspected diagnosis of heart failure, the results of this testing alone should not be used to confirm or exclude a heart failure diagnosis.

Key Words:
Brain natriuretic peptide, B-natriuretic peptide, BNP, heart failure, HF, congestive heart failure, CHF, dyspnea

Approved by Governing Bodies:
Elecsys® proBNP Immunoassay received FDA clearance November 19, 2002.
Triage® BNP test received FDA approval July 10, 2001.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity. Special benefit consideration may apply. Refer to member's benefit plan.
Pre-certification/Pre-determination requirements: Not applicable

Current Coding:

CPT codes: **83880** Natriuretic peptide

References:

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14. Mohideen, M.R. Brain natriuretic peptide is more than a marker, Ceylon Medical Journal, September 2002, Vol. 47, No. 3.
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16. Schillinger Martin. Cardiovascular risk stratification in older patients: role of brain natriuretic peptide, C-reactive protein, and urinary albumin levels, JAMA 2005; 293: 1667-1669.
17. U.S. Food and Drug Administration. New device clearance: Elecsys® proBNP immunoassay – K022516, www.fda.gov/cdrh/mda/docs/k022516.html.

Policy History:

Medical Policy Group, February 2004
Medical Policy Administration Committee, March 2004
Available for comment February 27-April 12, 2004
Medical Policy Group, December 2005 **(2)**
Medical Policy Administration Committee, December 2005
Available for comment December 27, 2005-February 9, 2006
Medical Policy Group, January 2007 **(1)**
Medical Policy Group, January 2009 **(1)**
Medical Policy Group, September 2011 **(3)**: Updated Key Points & References
Medical Policy Group, September 2012 **(3)**: **Active Policy but no longer scheduled for regular literature reviews and updates.**
Medical Policy Group, October 2013 **(3)**: Removed ICD-9 Diagnosis codes; no change to policy statement.