

Local Coverage Determination (LCD) for B-type Natriuretic Peptide (BNP) Testing (L31568)

Contractor Information

Contractor Name

Noridian Administrative Services, LLC

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Contractor Number

03402

Contractor Type

MAC - Part B

LCD Information

Document Information

LCD ID Number

L31568

Primary Geographic Jurisdiction

South Dakota

LCD Title

B-type Natriuretic Peptide (BNP) Testing

Oversight Region

Region X

Contractor's Determination Number

J3 CB2010. 02

Original Determination Effective Date

For services performed on or after 07/25/2011

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Original Determination Ending Date**Revision Effective Date**

For services performed on or after 07/25/2011

Revision Ending Date**CMS National Coverage Policy**

Title XVIII of the Social Security Act (SSA):

Section 1862(a)(1)(A) excludes expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Section 1862(a)(7) excludes routine physical examinations (screening).

Section 1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

Code of Federal Regulations:

42 CFR Sections 410.32(a) & 410.32(a)(3) require that clinical laboratory services be ordered and used promptly by the physician (or other treating practitioner acting within the scope of his or her license and Medicare requirements) who is treating the beneficiary.

42CFR411.15 excludes from coverage examinations performed for a purpose other than treatment or diagnosis of a specific illness, symptoms, complaint, or injury with specific legislative enactments as the only exceptions.

Indications and Limitations of Coverage and/or Medical Necessity

Abstract:

B-type natriuretic peptide (BNP) is a cardiac neurohormone produced mainly in the left ventricle. It is secreted in response to ventricular volume expansion and pressure overload, conditions often present in congestive heart failure (CHF). Used in conjunction with other clinical information, measurement of BNP levels (either total or N-terminal) is useful in rapidly establishing or excluding the diagnosis of CHF in patients with acute dyspnea. Also, BNP levels determined in the first few days after an acute coronary syndrome or event may be useful in the prediction of longer-term cardiovascular risk.

Indications:

BNP measurements may be considered reasonable and necessary when used in combination with other medical data such as medical history, physical examination, laboratory studies, chest x-ray, and electrocardiography in the following two clinical situations.

- Acute exacerbation of dyspnea in patients with known or suspected pulmonary or other non-cardiac causes of dyspnea to rule out CHF. Plasma BNP levels are significantly increased in patients with CHF presenting with acute dyspnea compared to patients presenting with acute dyspnea due to other causes.
- Acute exacerbation of dyspnea in patients known to suffer from both chronic obstructive pulmonary disease (COPD) and CHF. The BNP level may assist the physician distinguish between an exacerbation of COPD and decompensated CHF. Plasma BNP levels are significantly increased in patients with CHF with or without concurrent lung disease compared with patients who have primary lung disease.

Limitations:

BNP measurements must be assessed in conjunction with standard diagnostic tests, medical history and clinical findings. The efficacy of BNP measurement as a stand-alone test has not been established yet. Moreover, certain conditions such as (and not limited to) ischemia, infarction and renal insufficiency, advanced age, female gender may cause elevation of circulating BNP; obesity, upstream *heart failure* and other conditions lower the BNP level. These conditions confound the interpretation of BNP levels to varying extents.

The efficacy and/or utility of plasma BNP level as a monitor of the degree of CHF or the efficiency of CHF treatment has not been established. Treatment guided by BNP has not been shown to be superior to symptom-guided treatment in either clinical or quality of life outcomes. Therefore, BNP measurements for monitoring and management of CHF are non-covered.

The efficacy but not the utility of BNP as a risk stratification tool (to assess risk of death, myocardial infarction or congestive heart failure) among patients with acute coronary syndrome (myocardial infarction with or without T-wave elevation and unstable angina) has been established. However, the assessment of BNP level has not been shown to alter patient management. The BNP is not sufficiently sensitive to either preclude or necessitate any other evaluation or treatment in this group of patients.

Screening examinations are statutorily non-covered.

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Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

999x	Not Applicable
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Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

99999	Not Applicable
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CPT/HCPCS Codes

GroupName

83880	NATRIURETIC PEPTIDE
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ICD-9 Codes that Support Medical Necessity

It is the responsibility of the provider to code to the highest level specified in the *ICD-9-CM* (e.g., to the fourth or fifth digit). The correct use of an ICD-9-CM code listed below does not assure coverage of a service. The service must be reasonable and necessary in the specific case and must meet the criteria specified in this determination.

402.01	MALIGNANT HYPERTENSIVE HEART DISEASE WITH HEART FAILURE
402.11	BENIGN HYPERTENSIVE HEART DISEASE WITH HEART FAILURE
402.91	UNSPECIFIED HYPERTENSIVE HEART DISEASE WITH HEART FAILURE
404.01	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, MALIGNANT, WITH HEART FAILURE AND WITH CHRONIC KIDNEY DISEASE STAGE I THROUGH STAGE IV, OR UNSPECIFIED

404.03	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, MALIGNANT, WITH HEART FAILURE AND WITH CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
404.11	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, BENIGN, WITH HEART FAILURE AND WITH CHRONIC KIDNEY DISEASE STAGE I THROUGH STAGE IV, OR UNSPECIFIED
404.13	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, BENIGN, WITH HEART FAILURE AND CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
404.91	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, UNSPECIFIED, WITH HEART FAILURE AND WITH CHRONIC KIDNEY DISEASE STAGE I THROUGH STAGE IV, OR UNSPECIFIED
404.93	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, UNSPECIFIED, WITH HEART FAILURE AND CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
410.62	TRUE POSTERIOR WALL INFARCTION SUBSEQUENT EPISODE OF CARE
410.72	SUBENDOCARDIAL INFARCTION SUBSEQUENT EPISODE OF CARE
410.82	ACUTE MYOCARDIAL INFARCTION OF OTHER SPECIFIED SITES SUBSEQUENT EPISODE OF CARE
410.92	ACUTE MYOCARDIAL INFARCTION OF UNSPECIFIED SITE SUBSEQUENT EPISODE OF CARE
423.2	CONSTRICTIVE PERICARDITIS
425.4	OTHER PRIMARY CARDIOMYOPATHIES
428.0	CONGESTIVE HEART FAILURE UNSPECIFIED
428.1	LEFT HEART FAILURE
428.20	UNSPECIFIED SYSTOLIC HEART FAILURE
428.21	ACUTE SYSTOLIC HEART FAILURE
428.22	CHRONIC SYSTOLIC HEART FAILURE
428.23	ACUTE ON CHRONIC SYSTOLIC HEART FAILURE
428.30	UNSPECIFIED DIASTOLIC HEART FAILURE
428.31	ACUTE DIASTOLIC HEART FAILURE
428.32	CHRONIC DIASTOLIC HEART FAILURE
428.33	ACUTE ON CHRONIC DIASTOLIC HEART FAILURE
428.40	UNSPECIFIED COMBINED SYSTOLIC AND DIASTOLIC HEART FAILURE
428.41	ACUTE COMBINED SYSTOLIC AND DIASTOLIC HEART FAILURE
428.42	CHRONIC COMBINED SYSTOLIC AND DIASTOLIC HEART FAILURE
428.43	ACUTE ON CHRONIC COMBINED SYSTOLIC AND DIASTOLIC HEART FAILURE
428.9	HEART FAILURE UNSPECIFIED
491.21	OBSTRUCTIVE CHRONIC BRONCHITIS WITH (ACUTE) EXACERBATION
491.22	OBSTRUCTIVE CHRONIC BRONCHITIS WITH ACUTE BRONCHITIS
493.22	CHRONIC OBSTRUCTIVE ASTHMA WITH (ACUTE) EXACERBATION
493.92	ASTHMA UNSPECIFIED WITH (ACUTE) EXACERBATION
519.11	ACUTE BRONCHOSPASM
786.00	RESPIRATORY ABNORMALITY UNSPECIFIED
786.02	ORTHOPNEA
786.05	SHORTNESS OF BREATH

786.06	TACHYPNEA
786.07	WHEEZING
786.09	RESPIRATORY ABNORMALITY OTHER

Diagnoses that Support Medical Necessity

Not Applicable

ICD-9 Codes that DO NOT Support Medical Necessity

Not Applicable

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

Not Applicable

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General Information

Documentations Requirements

The patient's medical record must contain documentation that fully supports the medical necessity for services. (See "Indications and Limitations of Coverage.") This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

When requesting an *individual consideration* through the written redetermination (formerly appeal) process, providers must include all relevant medical records and literature that supports the request. At a minimum two (2) Phase II studies (human feasibility studies suggesting efficacy, pilots) or one (1) Phase III study (primary evidence of safety and efficacy, pivotal) must be submitted for the Medical Director's review.

Appendices Not Applicable

Utilization Guidelines

Sources of Information and Basis for Decision

Selected list

Bassan R, Tura BR, Maisel AS. B-type Natriuretic peptide: A strong predictor of early and late mortality in patients with acute chest pain without ST-segment elevation in the emergency department. *Coron Artery Disease*. 2009; 20:143-149.

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- Latini R, Masson S, Wong M, et. al. Incremental prognostic value of changes in B-type natriuretic peptide in heart failure. *American Journal of Medicine,* 2006;119(1):70e24-70.
- Le Jemtel TH, Padeletti M, Jelic S. Diagnostic and therapeutic challenges in patients with coexistent chronic obstructive pulmonary disease and chronic heart failure. *J AM Coll Cardiol.* 2007; 49 (2): 171-180.

Logeart D, Thabut G, Jopurdain P et al. Predischarge B-type Natriuretic peptide assay for identifying patients at high risk of re-admission after decompensated heart failure. *J Am Coll Cardiol*. 2004;43(4):635-641.

Lubien E, DeMaria A, Krishnaswamy P, et al. Utility of B-natriuretic peptide in detecting diastolic dysfunction: comparison with Doppler velocity recordings. *Circulation*. 2002;105(5):595-601.

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Solinas L, Raucci R, Terrazzino S et al. Prevalence, clinical characteristics, resource utilization and outcome of patients with acute chest pain in the emergency department. A multicenter, prospective, observational study in north-eastern Italy. *Ital Heart J*. 2003;4(5):318-324.

Wieczorek S, Wu A, Christenson R, et al. A rapid B-type natriuretic peptide assay accurately diagnoses left ventricular dysfunction and heart failure: a multicenter evaluation. *Am Heart J*. 2002;144(5):834-839.

Wu A, Omland T, Duc P, et al. The effect of diabetes on B-type natriuretic peptide concentrations in patients with acute dyspnea: an analysis from the Breathing Not Properly (BNP) Multinational Study. <http://care.diabetesjournals.org/cgi/content/full/27/10/2398>. Accessed April 7, 2005.

Young J, Supplement Ed and Roundtable Moderator. Testing for B-type natriuretic peptide in the diagnosis and assessment of heart failure: what are the nuances? *Cleve Clin J Med*. 2004;71(Supplement 5):S1-S17.

<http://www.ccjm.org/toc/BNP.htm>. Accessed April 5, 2005. **Advisory Committee Meeting Notes** This LCD was originally discussed at the July 8, 2010 Part A Open Door Coverage Meeting and presented at the January 18, 2011 Open Public Meeting and the following Part B Carrier Advisory Committee Meetings:

Arizona February 8, 2011
Montana March 3, 2011
North Dakota February 15, 2011
South Dakota February 17, 2011
Utah February 10, 2011
Wyoming February 10, 2011

Response to Part A Provider Recommendations from the July Part A Open Door Coverage meeting draft LCD:

Comment: We received one written request to expand the Indications list to include risk stratification among patients with acute coronary artery syndrome (ACS).

Response: This indication will not be added to the list of reimbursable conditions. Evidence of the usefulness of BNP in this condition is not straightforward. The most recent (2010) systematic review concluded the literature did not establish the utility of the test in predicting either MI or rehospitalization following ACS. Moreover, even if the evidence were clear, there is no evidence the clinical lab test results alter patient management as is required for Medicare reimbursement [42CFR410.32(a)]. Patients who present with ACS receive maximal tolerated therapy regardless of the test results, both medical and surgical. The BNP test is insufficiently sensitive to preclude any therapy. It is also inadequate to direct therapy to either a medical or surgical path: "The therapeutic benefits that can be derived from BNP and NT-proBNP assessment in ACS are not clear with respect to invasive versus conservative management" -McCullogh et al 2010; and most patients undergo surgical interventions, regardless of BNP results.

Comment: Noridian received two written requests to expand the indications list to include monitoring the course of heart failure therapy.

Response: This indication will not be added to the list of reimbursable conditions. All recent literature indicates that symptom-guided therapy is equal or superior to BNP-guided therapy, both in overall clinical outcomes and quality of life. (In part, this finding may be related to the absence of any proven effective treatment for heart failure with preserved ejection fraction, which is common in older patients; hence, treatment is necessarily focused most productively on the reduction of symptoms.)

Comment: One practitioner requested the addition of "suspected" pulmonary disease to the first indication, differentiation of known or "suspected" pulmonary disease from heart failure.

Response: The recommendation is accepted. The cause of the dyspnea does not need to be known. However, the physician must have documented sufficient information to indicate a reason for the suspicion of pulmonary or other non-cardiac cause of the dyspnea.

Comment: We received requests for the addition of codes: swelling of limb, edema, fluid retention

Response: The codes will not be added. The codes are sufficiently non-specific to allow indications not intended by the LCD.

NAS Response to Provider Recommendation (for comment period ending 05/11/2011):

Comment: We received a lengthy, thoughtful request for coverage of BNP in the role of risk stratification for Acute Coronary Syndrome, including references to literature purported to support that request.

Response: We have reviewed this information before. No cardiologist we queried would withhold any diagnostic or therapeutic intervention in any group of cardiac patients based on BNP findings. In addition, none of them altered management based on the test. It appears to us that the test, at best, is used to add strength to a practitioner's conclusions re patient status. Many of the MDs we spoke with believe the test is entirely superfluous. Thus, we have not added this requested coverage.

Comment: One final comment repeated the recommendation that BNP-guided therapy be covered, due to the assertion that "...more data has become available..." supporting BNP-guided therapy.

Response: NAS has reviewed all the pertinent literature, including that supplied in this comment. The data simply do not support the assertion that BNP-guided therapy is clearly superior to symptom-guided treatment. NAS does not accept this recommendation. (Please see references.)

Comment: One comment recommended addition of a list of several ICD-9 diagnosis codes.

Response: Upon review, NAS believes that the current list of covered diagnosis codes is appropriate and that addition of those recommended by the commenter are not supported by the weight of evidence. NAS will not add further ICD-9 codes at this time.

Start Date of Comment Period 01/18/2011

End Date of Comment Period 05/15/2011

Start Date of Notice Period 06/09/2011

Revision History Number 02

Revision History Explanation 03/31/2011 - The MCD did not publically display the address for submission of comments to this draft LCD. Therefore, NAS is extending the formal Comment Period from 04/20/11 to 05/15/2011 and published a notification to this effect on noridianmedicare.com as well.

Comments may be submitted to:
Noridian Administrative Services, LLC
Attn: Part B Contractor Medical Director(s)
PO BOX 6740
Fargo ND 58108-6740

policyb.drafts@noridian.com

J3 CB2010.02

06/01/2011 - released to final

Reason for Change Other

Related Documents

This LCD has no Related Documents.

LCD Attachments

There are no attachments for this LCD.

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All Versions

Updated on 06/02/2011 with effective dates 07/25/2011 - N/A

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