

LCD for Vitamin B 12 Injection (L28315)

Contractor Information

Contractor Name

Palmetto GBA

Contractor Number

01102

Contractor Type

MAC - Part B

LCD Information

LCD ID Number

L28315

LCD Title

Vitamin B 12 Injection

Contractor's Determination Number

J1B-08-0087-L

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CMS National Coverage Policy

Title XVIII of the Social Security Act, §1862(a)(1)(A). Allows coverage and payment for only those services that are considered to be medically reasonable and necessary.

Title XVIII of the Social Security Act, §1833(e). Prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 3, §3.4.1.1.E. Claims submitted by physicians or practitioners must contain diagnosis codes.

Primary Geographic Jurisdiction

California - Northern

Oversight Region

Region X

Original Determination Effective Date

For services performed on or after 09/02/2008

Original Determination Ending Date

Revision Effective Date

For services performed on or after 11/12/2009

Revision Ending Date

Indications and Limitations of Coverage and/or Medical Necessity

Vitamin B12 (cyanocobalamin, B12) is an essential vitamin necessary for cell maturation. B12 deficiency may be caused by several pathological and post-surgical conditions and its presence can be assessed by B12 serum assays. This deficiency can lead to profound hematological and neurological damage, and may be corrected by oral B12, intranasal B12 gel or intramuscular or deep subcutaneous injection. This policy will cover only the intramuscular or deep subcutaneous injection of B12 since the other two modes of replacement are both self-administered and so are not Medicare benefits.

This policy will also not discuss tests used to determine the cause of the B12 deficiency, e.g., the Schilling test, but will focus on the injection of B12 to correct the deficiency from whatever cause.

The **only** indication for Vitamin B12 injection that justifies medical necessity is Vitamin B12 deficiency. While B12 deficiency has many causes, few of these causes will always lead to B12 deficiency. Accordingly, the physician should not give B12 just because the patient has one of the causes, but only after a deficiency has been documented by serum assay. Consistent with this A/B MAC's position that **payment** should be based on the sign or symptom being treated rather than the underlying cause, payment will be based solely on the presence of one of the diagnosis codes listed in this LCD, though the underlying diagnosis code may be billed if desired. The two causes that are exceptions to this statement are total gastrectomy and total ileal resection, both leading invariably to B12 deficiency.

The term, B12 deficiency, needs comment. **The Laboratory Test Handbook**, 2002, (p. 375) states: "The lower reference limit, which is critical to the diagnosis of cobalamin (vitamin B12) deficiency/pernicious anemia, is not clearly established. It is likely in the range of 100-250 pg/mL (SI:74-185 pmol/L). Values are method and laboratory dependent. Because of overlap in serum levels between cobalamin-deficient and normal individuals, use of an indeterminate interval is necessary. The following are interpretive intervals for serum cobalamin:

- normal: 200-900 pg/mL
- indeterminate: 160-200 pg/mL
- low: <160 pg/mL

Clinical correlation and multiple test documentation of the etiology of macrocytic anemia are advised. Occasionally, patients with significant neuropsychiatric abnormalities may have no hematologic abnormalities (absence of anemia or macrocytosis), but vitamin B12 level <200 pg/mL (SI <150 pmol/L)." End of Quote

Further, **Harrison's Principles of Internal Medicine**, 2001 (p. 679) states: "Serum methylmalonic acid and homocysteine levels "are elevated in cobalamin deficiency" These tests measure tissue vitamin stores and may demonstrate a deficiency even when the more traditional but less reliable folate and cobalamin levels are borderline or even normal. Patients (particularly older patients) without anemia and with normal serum cobalamin levels but elevated levels of serum methylmalonic acid may develop neuropsychiatric abnormalities. Treatment of patients with this "subtle" cobalamin deficiency will usually prevent further deterioration and may result in improvement." End of Quote (Please note that this statement does not appear in the 2005 Harrison's.)

Note that serum methylmalonic acid is not listed in the 2006 AMA CPT manual. Neither methylmalonic acid nor homocystine test is cost-effective in most circumstances. Accordingly, this policy suggests that when a patient shows neuropsychiatric abnormalities, and the serum B12 is low normal, i.e., below 350 pg/ml, the physician may, in the absence of methylmalonic acid or homocysteine tests, presume a B12 deficiency and treat the patient with B12.

This A/B MAC will leave the choice of treatment regimens for this condition to the providing physician, but notes that the treatment of a sudden deficiency (post-gastric resection) will generally be different from treatment of a slowly developing deficiency (pernicious anemia).

Compliance with the provisions in this policy is subject to monitoring by post payment data analysis and subsequent medical review.

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

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

CPT/HCPCS Codes

CPT/HCPCS Codes

96372

THERAPEUTIC, PROPHYLACTIC, OR
DIAGNOSTIC INJECTION (SPECIFY SUBSTANCE
OR DRUG); SUBCUTANEOUS OR
INTRAMUSCULAR

J3420

INJECTION, VITAMIN B-12 CYANOCOBALAMIN,
UP TO 1000 MCG

ICD-9 Codes that Support Medical Necessity

These are the only covered diagnoses for HCPCS code J3420:

123.4	DIPHYLLOBOTHRIASIS INTESTINAL
266.2	OTHER B-COMPLEX DEFICIENCIES
281.0	PERNICIOUS ANEMIA
281.1	OTHER VITAMIN B12 DEFICIENCY ANEMIA
281.3	OTHER SPECIFIED MEGALOBLASTIC ANEMIAS NOT ELSEWHERE CLASSIFIED
287.5	THROMBOCYTOPENIA UNSPECIFIED
V58.49	OTHER SPECIFIED AFTERCARE FOLLOWING SURGERY
V58.69	LONG-TERM (CURRENT) USE OF OTHER MEDICATIONS

Diagnoses that Support Medical Necessity

All ICD-9-CM codes listed in this policy under ICD-9-CM Codes That Support Medical Necessity above.

ICD-9 Codes that DO NOT Support Medical Necessity

All ICD-9-CM codes not listed in this policy under ICD-9-CM Codes That Support Medical Necessity above.

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

Diagnoses that DO NOT Support Medical Necessity

All ICD-9-CM codes not listed in this policy under ICD-9-CM Codes That Support Medical Necessity above.

General Information

Documentation Requirements

The clinical record must include a laboratory report on the serum assay for B12 and this assay must show B12 deficiency. There are two exceptions to this rule. Since adequate absorption of dietary B12 requires a functioning stomach and ileum, complete surgical resection of either the stomach or ileum can be presumed to always lead to B12 deficiency, and that diagnosis may be presumed without a serum B12 assay.

The medical record must be made available to Medicare upon request.

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing Medicare.

When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary.

When requesting a written redetermination (formerly appeal), providers must include all relevant documentation with the appeal request.

Appendices

Utilization Guidelines

The frequency of B12 injections should conform to one of the regimens noted above under Indications and Limitations of Coverage and/or Medical Necessity. If there is a deviation from one of these regimens, the clinical record should document the reason for the deviation.

Sources of Information and Basis for Decision

USP DI. Micromedex, Englewood, CO. 2005;1:2955.

AHFS Drug Information., American Hospital Formulary Service, Bethesda, MD. 2006:3564.

Braunwald, et al. eds. *Harrison's Principles of Internal Medicine*, New York: McGraw Hill. 2001:680.

Braunwald, et al. eds. *Harrison's Principles of Internal Medicine*, New York: McGraw Hill. 2005.

Jacobs, et al. eds. *Laboratory Test Handbook*, Cleveland, LEXI-COMP INC. 2nd Ed. 2002:375.

Other carriers' LMRPs/LCDs

Advisory Committee Meeting Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which include representatives from the affected provider community.

Contractor Advisory Committee meeting dates:

California -

Hawaii -

Nevada -

Start Date of Comment Period

End Date of Comment Period

Start Date of Notice Period

06/16/2008

Revision History Number

Revision #4

Revision History Explanation

Revision #4 effective for dates of service on or after 11/12/2009

Revision made: Under CMS National Coverage Policy" added reference Pub 100-08, *Medicare Program Integrity Manual*, Chapter 3, §3.4.1.1,E. Annual review and validation completed.

Revision #3, 02/26/2009

This LCD is being revised to implement the streamlining of the Part B LCDs per the published article "Palmetto Team to Streamline Part B LCDs in Jurisdiction 1 (J1)." This article can be viewed at www.PalmettoGBA.com by searching for the above article name. This revision will become effective on 02/26/2009.

Revision #2 effective for dates of service on or after 01/01/2009

Revision made: 2009 Annual CPT Update; addition of CPT code 96372, removal of deleted CPT code 90772. "CMS National Coverage Policy" section removed duplicative wording. Under "Documentation Requirements" removed duplicate reference cited previously in "CMS National Coverage Policy." "Sources of Information and Basis for Decision" references placed in AMA citation format. This LCD will become effective on 01/01/2009.

Revision #1, 09/02/2008

This LCD is being revised to add Bill Type 999X because the automated system transcription process was incomplete.

11/09/2008 - CPT/HCPCS code 90772 was deleted from group 1

Reason for Change

Last Reviewed On Date

11/02/2009

Related Documents

This LCD has no Related Documents.

LCD Attachments

There are no attachments for this LCD.

All Versions

Updated on 11/03/2009 with effective dates 11/12/2009 - N/A

Updated on 02/19/2009 with effective dates 02/26/2009 - 11/11/2009

Updated on 12/05/2008 with effective dates 01/01/2009 - 02/25/2009

Updated on 07/26/2008 with effective dates 09/02/2008 - 12/31/2008

Updated on 06/08/2008 with effective dates 09/02/2008 - N/A