

Local Coverage Determination (LCD): Vitamin D Assay Testing (L36692)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01911 - MAC A	J - E	American Samoa California - Entire State Guam Hawaii Nevada Northern Mariana Islands

LCD Information

Document Information

LCD ID

Original Effective Date

L36692

For services performed on or after 02/03/2017

LCD Title

Vitamin D Assay Testing

Revision Effective Date

For services performed on or after 12/01/2019

Proposed LCD in Comment Period

N/A

Revision Ending Date

N/A

Source Proposed LCD

DL36692

Retirement Date

N/A

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

CPT codes, descriptions and other data only are copyright 2019 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply.

Notice Period Start Date

12/19/2016

Notice Period End Date

02/02/2017

Current Dental Terminology © 2019 American Dental Association. All rights reserved.

Copyright © 2019, the American Hospital Association, Chicago, Illinois. Reproduced with permission. No portion of the AHA copyrighted materials contained within this publication may be copied without the express written consent of the AHA. AHA copyrighted materials including the UB-04 codes and descriptions may not be removed, copied, or utilized within any software, product, service, solution or derivative work without the written consent of the AHA. If an entity wishes to utilize any AHA materials, please contact the AHA at 312-893-6816. Making copies or utilizing the content of the UB-04 Manual, including the codes and/or descriptions, for internal purposes, resale and/or to be used in any product or publication; creating any modified or derivative work of the UB-04 Manual and/or codes and descriptions; and/or making any commercial use of UB-04 Manual or any portion thereof, including the codes and/or descriptions, is only authorized with an express license from the American Hospital Association. To license the electronic data file of UB-04 Data Specifications, contact Tim Carlson at (312) 893-6816 or Laryssa Marshall at (312) 893-6814. You may also contact us at ub04@healthforum.com.

CMS National Coverage Policy

Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items

or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.

Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.

Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.

42CFR410.32(a) requires a clinical diagnostic test be ordered by the physician who is treating the patient for a specific medical problem and uses the results in the management of the beneficiary's specific problem.

MBPM Internet Only Manual(IOM 100-02), chap. 6, §20.4.3 applies 42CFR410.32 to hospitals.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Vitamin D is called a "vitamin" because of its exogenous source, predominately from oily fish in the form of vitamin D₂ and vitamin D₃. It is more accurate to consider fat-soluble Vitamin D as a steroid hormone, synthesized by the skin and metabolized by the kidney to an active hormone, calcitriol. Clinical disorders related to vitamin D may arise because of altered availability of the parent vitamin D, altered conversion of vitamin D to its predominant metabolites, altered organ responsiveness to dihydroxylated metabolites and disturbances in the interactions of the vitamin D metabolites with PTH and calcitonin. Normal levels of Vitamin D range from 20 – 50 ng/dl. This LCD identifies the indications and limitations of Medicare coverage and reimbursement for the lab assay.

Indications:

Measurement of 25-OH Vitamin D level is indicated for patients with:

- chronic kidney disease stage III or greater
- cirrhosis
- hypocalcemia
- hypercalcemia
- hypercalciuria

- hypervitaminosis D

- parathyroid disorders

- malabsorption states

- obstructive jaundice

- osteomalacia

- osteoporosis if
 - i. T score on DEXA scan
 - ii. History of fragility fractures or
 - iii. FRAX > 3% 10-year probability of hip fracture or 20% 10-year probability of other major osteoporotic fracture or
 - iv. FRAX > 3% (any fracture) with T-score v. Initiating bisphosphonate therapy (Vit D level should be determined and managed as necessary

before bisphosphonate is initiated)

- osteosclerosis/petrosis
- rickets
- vitamin D deficiency on replacement therapy related to a condition listed above; to monitor the efficacy of treatment.

Measurement of 1, 25-OH Vitamin D level is indicated for patients with:

- unexplained hypercalcemia (suspected granulomatous disease or lymphoma)

- unexplained hypercalciuria (suspected granulomatous disease or lymphoma)

- suspected genetic childhood rickets

- suspected tumor-induced osteomalacia

- nephrolithiasis or hypercalciuria

Limitations:

Testing may not be used for routine or other screening.

Both assays of vitamin D need not be performed for each of the above conditions. Often, one type is more appropriate for a certain disease state than another. The most common type of vitamin D deficiency is 25-OH vitamin D. A much smaller percentage of 1, 25-dihydroxy vitamin D deficiency exists; mostly, in those with renal disease. Although it is not the active form of the hormone, 25-OH vitamin D is much more commonly measured because it better reflects the sum total of vitamin D produced endogenously and absorbed from the diet than does the level of the active hormone 1, 25-dihydroxy vitamin D. Deficiency of 1, 25-dihydroxy vitamin D, which is present at much lower concentrations, does not necessarily reflect deficiency of 25-OH vitamin D and its measurement should be limited to the indications listed. Documentation must justify the test(s) chosen for a particular disease entity. Various component sources of 25-OH vitamin D, such as stored D or diet-derived D, should not be billed separately.

Once a beneficiary has been shown to be vitamin D deficient, further testing may be medically necessary only to ensure adequate replacement has been accomplished. If Vitamin D level is between 20 and 50 ng/dl and patient is clinically stable, repeat testing is often unnecessary; if performed, documentation must clearly indicate the necessity of the test. If level 60 ng/dl, a subsequent level(s) may be reimbursed until the level is within the normal range.

Summary of Evidence

N/A

**Analysis of Evidence
(Rationale for Determination)**

N/A

General Information

Associated Information

Documentation must clearly indicate the necessity for the test(s), any and all repeat testing and frequency of testing.

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

Sources of Information

1. IOM (Institute of Medicine). *Dietary Reference Intake for Calcium and Vitamin D*. 2011. Washington D.C.: the National Academies Press
2. American Medical Association (AMA). Council on Science and Public Health "Appropriate Supplementation of Vitamin D," CSAPH Report 4-A-09.
3. Autier P, Gandini S. Vitamin D Supplementation and Total Mortality. A Meta-analysis of Randomized Controlled Trials. *Arch Intern Med*. 2007;167(16);1730-1737.
4. Bischoff-Ferrari HA, Dawson-Hughes B, Willett W, et al. Effect of vitamin D on falls a meta-analysis. *JAMA* April 2004;291:16:1999-2006. www.jama.com. Accessed 03/04/2009.
5. Bischoff-Ferrari HA, Dietrich T, Orav EJ, Dawson-Hughes B. Positive association between 25-Hydroxy vitamin D levels and bone mineral density: a population-based study of younger and older adults. *The American Journal of Medicine*. 2004;116:634-639.
6. Bischoff-Ferrari HA, Willett W, Wong J, Giovannucci E, Dietrich T, Dawson-Hughes B. Fracture prevention with vitamin D supplementation, a meta-analysis of randomized controlled trials. *JAMA*. May 2005;293:18:2257-2264. www.jama.com. Accessed 03/04/2009.
7. Bodnar LM, Simhan HN, Powers RW, Frank MP, Cooperstein E, Roberts JM. High prevalence of vitamin D insufficiency in black and white pregnant women residing in the northern United States and their neonates. *J Nutr*. 2007;137:447-452. <http://jn.nutrition.org>. Accessed 02/10/2009.
8. Cannell JJ. Autism and Vitamin D. *Med Hypotheses*. 2008;70:4:750-759. <http://www.ncbi.nlm.nih.gov/pubmed/17920208>. Accessed 02/10/2009.
9. Cannell JJ, Hollis BW, Zasloff M, Heaney RP. Diagnosis and treatment of vitamin D deficiency. *Expert Opin Pharmacother*. 2008;9:1-12.
10. Chapuy M, Arlot M, Duboeuf F, et al. vitamin D3 and calcium to prevent hip fractures in elderly women. *The New England Journal of Medicine*. December 1992;327:23:1637-1641.
11. Chronic Kidney Disease 2006: A Guide to Select NKF-KDOQI Guidelines and Recommendations.
12. Woolcott CG, Wilkens LR, Nomura AM et al. Plasma 25-hydroxyvitamin D levels and the risk of colorectal cancer: the multiethnic cohort study. *Cancer Epidemiol Biomarkers Prev* 2010; 19(1):130-134.
13. *Vitamin D and Calcium Systematic Review of Health Outcomes*. Structured Abstract. Agency for Healthcare Research and Quality. Rockville, MD. <http://www.ahrq.gov/clinic/tp/vitadcaltp.htm>
14. MacLean C, Alexander A, Carter J et al. *Comparative Effectiveness of Treatments to Prevent Fractures in Men and Women with Low Bone Density or Osteoporosis Executive Summary*. No.12 (Prepared by Southern California/RAND Evidence-based Practice Center under Contract with the Agency for Healthcare Research and Quality. December 2007.

15. *Vitamin D Evidence-based Monograph*. The Natural Standard Research Collaboration. (Last updated June 1, 2010.) <http://naturalstandard.com>; and <http://www.mayoclinic.com/health/vitamin-d>
16. Bjelakovic, Goran, Gluud et al. *Vitamin D* supplementation for prevention of mortality in adults. (Protocol) Cochrane Database of Systematic Reviews 2008, Issue 4. Art. No.,: CD007470. DOI:10.1002/14651858.CD007470. [Last review 2010; no changes to last published edit 03 May 2009.]
17. Giovannucci E, Liu Y, Hollis BW, Rimm EB. 25-Hydroxyvitamin D and Risk of Myocardial Infarction in Men; A Prospective Study. *Arch Intern Med*.2008;168(11):1174-1180.
18. Wagner CL, Greer FR, and the Section on Breastfeeding and Committee on Nutrition. Prevention of Rickets and Vitamin D Deficiency in Infants, Children, and Adolescents. [published correction appears in *Pediatrics* 2009;123;197.]. *Pediatrics* 2008;122;1142-1152.
19. Lafferty, FW. Differential diagnosis of hypercalcemia. *J Bone Miner Res* 1991; 6 Suppl 2:S51.
20. Silverberg S, Bilezikian. Primary Hyperparathyroidism. In: *Primer on Metabolic Bone Diseases and Disorders of Mineral Metabolism*. 7th ed., 2008:7:302-306.
21. Horwitz M, Hodak S, Stewart A. Non-Parathyroid Hypercalcemia. In: *Primer on Metabolic Bone Diseases and Disorders of Mineral Metabolism*. 7th ed., 2008:7:307-312.
22. *Am. J. Med.* 107(6):561-567(1999), "The effects of vitamin D insufficiency in patients with primary hyperparathyroidism", Silverberg, S.J., et.al.
23. Schilling, T, Pecherstorfer, M, Blind, E, et al. Parathyroid hormone-related protein (PTH-rP) does not regulate serum 1,25-dihydroxyvitamin D levels in hypercalcemia of malignancy. *J Clin Endocrinol Metab* 1993; 76:801.
24. Jacobus, CH, Holick, MF, Shao, Q, et al. Hypervitaminosis D associated with drinking milk. *N Engl J Med* 1992; 326:1173.
25. Goltzman, D, Cole, DEC. Hypoparathyroidism. In *Primer on the Metabolic Bone Diseases and Disorders of Bone Metabolism*, American Society of Bone and Mineral Research 2006; 6:216.
26. Bernstein, CN, Leslie, WD, Leboff, MS. AGA technical review on osteoporosis in gastrointestinal diseases. *Gastroenterology* 2003; 124:795.
27. Johnson, JM, Maher, JW, Demaria, EJ, et al. The Long-term Effects of Gastric Bypass on Vitamin D Metabolism. *Ann Surg* 2006; 243:701.
28. American Gastroenterological Association medical position statement: guidelines on osteoporosis in gastrointestinal diseases. *Gastroenterology* 2003; 124:791.
29. Hahn, TJ. Drug-induced disorders of vitamin D and mineral metabolism. *Clin Endocrinol Metab* 1980; 9:107.
30. Sotaniemi, EA, Hakkarainen, HK, Puranen, JA, Lahti, RO. Radiologic bone changes and hypocalcemia with anticonvulsant therapy in epilepsy. *Ann Intern Med* 1972; 77:389.
31. Välimäki, MJ, Tiihonen, M, Laitinen, K, et al. Bone mineral density measured by dual-energy X-ray absorptiometry and novel markers of bone formation and resorption in patients on antiepileptic drugs. *J Bone Miner Res* 1994; 9:631.

32. Compston, JE. Hepatic osteodystrophy: Vitamin D metabolism in patients with liver disease. *Gut* 1986; 27:1073.
33. Holick, MF. Vitamin D deficiency. *N Engl J Med* 2007; 357:266.
34. Am. J. Kidney Dis. 50(1):59-68(2007) "Changes in serum 25-hydroxyvitamin D and plasma intact PTH levels following treatment with ergocalciferol in patients with CKD", Al Aly, Z, et. al.
35. Bone, (2008), "Serum 25-hydroxyvitamin D as an independent determinant of 1-84 PTH and bone mineral density in non-diabetic predialysis CKD patients", Tomida, K., et. al.
36. Ceglia L. Vitamin D and skeletal muscle tissue and function. *Mol Aspects Med.* 2008 Dec;29(6):407-14. Epub 2008 Aug 8. Review.
37. Ward KA, Das G, Berry JL, Roberts SA, Rawer R, Adams JE, Mughal Z. Vitamin D status and muscle function in post-menarchal adolescent girls. *J Clin Endocrinol Metab.* 2009 Feb;94(2):559-63. Epub 2008 Nov 25.
38. Gordon PL, Sakkas GK, Doyle JW, Shubert T, Johansen KL. Relationship between vitamin D and muscle size and strength in patients on hemodialysis. *J Ren Nutr.* 2007 Nov;17(6):397-407. PubMed PMID: 17971312.
39. Hollick MF High Prevalence of Vitamin D Inadequacy and Implications for Health *Mayo Clin Proc.* 2006;81(3):353-373.
40. Buischoff-Ferrari, HA et al Estimation of optimal serum concentrations of 25-hydroxyvitamin D for multiple health outcomes *Am J Clin Nutr* (2006) 84:18.
41. Ybarra J, Sánchez-Hernández J, Pérez A. Hypovitaminosis D and morbid obesity. *Nurs Clin North Am.* 2007 Mar;42(1):19-27, v. Review.
42. Goldner WS, Stoner JA, Thompson J, Taylor K, Larson L, Erickson J, McBride C. Prevalence of vitamin D insufficiency and deficiency in morbidly obese patients: a comparison with non-obese controls. *Obes Surg.* 2008 Feb;18(2):145-50.
43. Sánchez-Hernández J, Ybarra J, Gich I, De Leiva A, Rius X, Rodríguez-Espinosa J, Pérez A. Effects of bariatric surgery on vitamin D status and secondary hyperparathyroidism: a prospective study. *Obes Surg.* 2005 Nov-Dec;15(10):1389-95.
44. Lee JH, O'Keefe JH, Bell D et al. Vitamin D deficiency. *JACC.* 2008; 52(24):1949-56.
45. Lapp JL. Vitamin D: bone health and beyond. *Am J Lifestyle Med.* 2009;3:386-93.
46. Binkley N, Krueger D, Gemar D, Drezner MK. Correlation among 25-hydroxy-vitamin D assays. *J Clin Endocrinol Metab.* 2008; 93:1804-1808
47. Bolland MJ, Bacon CJ, Horne AM et al. Vitamin D Insufficiency and Health. *Am J Clin Nutr* 2010; 91:82-89.
48. Other Contractor(s)' Policies.

Bibliography

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
12/01/2019	R4	<p>The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</p>	<ul style="list-style-type: none"> Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.)
12/01/2019	R3	<p>12/01/2019: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</p> <p>As required by CR 10901, all billing and coding information has been moved to the companion article, this article is linked to the LCD</p>	<ul style="list-style-type: none"> Provider Education/Guidance Revisions Due To Code Removal
10/01/2018	R2	<p>At this time 21st Century Cures Act will apply to new and revised Articles that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the Article are applicable as noted in this policy.</p> <p>08/09/2018 - For the following ICD-10 code descriptions were changed in the ICD-10 Codes that Support Medical Necessity field: Z68.43 descriptor was changed in Group 1 Effective 10/01/2018</p>	<ul style="list-style-type: none"> Revisions Due To ICD-10-CM Code Changes
02/03/2017	R1	<p>Codes added from 2016 ICD-10 Coding update E89.820; E89.821; E89.822; E89.823</p>	<ul style="list-style-type: none"> Revisions Due To ICD-10-CM Code Changes

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A57718 - Billing and Coding: Vitamin D Assay Testing

A55372 - Response to Comments: Vitamin D Assay Testing

LCD(s)

DL36692

- (MCD Archive Site)

Related National Coverage Documents

N/A

Public Version(s)

Updated on 01/29/2020 with effective dates 12/01/2019 - N/A

Updated on 11/08/2019 with effective dates 12/01/2019 - N/A

Updated on 09/10/2018 with effective dates 10/01/2018 - 11/30/2019

Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

Keywords

N/A