Local Coverage Determination (LCD): Vitamin D Assay Testing (L33556)

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Contractor Information

Contractor Name National Government Services, Inc. Back to Top

Contract Number 06201

Contract Type MAC - Part A

LCD Information

Document Information

LCD ID L33556

Original ICD-9 LCD ID L29510

LCD Title Vitamin D Assay Testing

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Jurisdiction Minnesota

Original Effective Date For services performed on or after 10/01/2015

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Revision Ending Date N/A

Retirement Date N/A

Notice Period Start Date

N/A

CMS National Coverage Policy Language quoted from Centers for Medicare and Medicaid Services (CMS). National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals is italicized throughout the Printed on 12/10/2015. Page 1 of 8

policy. NCDs and coverage provisions in interpretive manuals are not subject to the Local Coverage Determination (LCD) Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See Section 1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, italicized text represents quotation from one or more of the following CMS sources:

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

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Abstract:

Vitamin D is a hormone, synthesized by the skin and metabolized by the kidney to an active hormone, calcitriol. An excess of vitamin D may lead to hypercalcemia. Vitamin D deficiency may lead to a variety of disorders. This LCD identifies the indications and limitations of Medicare coverage and reimbursement for these services.

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 really a hormone, synthesized by the skin and metabolized by the kidney to an active hormone, calcitriol, which then acts throughout the body. In the skin, 7-dehydrocholesterol is converted to vitamin D3 in response to sunlight, a process that is inhibited by sunscreen with a skin protection factor (SPF) of 8 or greater. Once in the blood, vitamin D2 and D3 from diet or skin bind with vitamin D binding protein and are carried to the liver where they are hydroxylated to yield calcidiol. Calcidiol then is converted in the kidney to calcitriol by the action of 1a-hydroxylase (CYP27B1). The CYP27B1 in the kidney is regulated by nearly every hormone involved in calcium homeostasis, and its activity is stimulated by PTH, estrogen, calcitonin, prolactin, growth hormone, low calcium levels, and low phosphorus levels. Its activity is inhibited by calcitriol, thus providing the feedback loop that regulates calcitriol synthesis.

An excess of vitamin D is unusual, but may lead to hypercalcemia. Vitamin D deficiency may lead to a variety of disorders, the most infamous of which is rickets. Evaluating patients' vitamin D levels is accomplished by measuring the level of 25-hydroxyvitamin D. Measurement of other metabolites is generally not medically necessary.

Indications:

Measurement of vitamin D levels is indicated for patients with:

- chronic kidney disease stage III or greater;
- osteoporosis;
- osteomalacia;
- osteopenia;
- hypocalcemia;
- hypercalcemia;
- hypoparathyroidism;
- hyperparathyroidism;
- hypervitaminosis D;
- rickets; and
- vitamin D deficiency to monitor the efficacy of replacement therapy.

Limitations:

For Medicare beneficiaries, screening tests are governed by statute. Vitamin D testing may not be used for routine screening.

Once a beneficiary has been shown to be vitamin D deficient, further testing is medically necessary only to ensure adequate replacement has been accomplished. Thereafter, annual testing may be appropriate depending upon the indication and other mitigating factors.

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.

011x Hospital Inpatient (Including Medicare Part A)

012x Hospital Inpatient (Medicare Part B only)

013x Hospital Outpatient

014x Hospital - Laboratory Services Provided to Non-patients

018x Hospital - Swing Beds

021x Skilled Nursing - Inpatient (Including Medicare Part A)

022x Skilled Nursing - Inpatient (Medicare Part B only)

023x Skilled Nursing - Outpatient

071x Clinic - Rural Health

072x Clinic - Hospital Based or Independent Renal Dialysis Center

073x Clinic - Freestanding

077x Clinic - Federally Qualified Health Center (FQHC)

085x Critical Access Hospital

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.

Revenue codes only apply to providers who bill these services to the Part A MAC. Revenue codes do not apply to physicians, other professionals and suppliers who bill these services to the Part B MAC.

Please note that not all revenue codes apply to every type of bill code. Providers are encouraged to refer to the FISS revenue code file for allowable bill types. Similarly, not all revenue codes apply to each CPT/HCPCS code. Providers are encouraged to refer to the FISS HCPCS file for allowable revenue codes.

All revenue codes billed on the inpatient claim for the dates of service in question may be subject to review.

0300 Laboratory - General Classification

0301 Laboratory - Chemistry

0309 Laboratory - Other Laboratory

CPT/HCPCS Codes

Group 1 Paragraph: N/A

Group 1 Codes:

82306 VITAMIN D; 25 HYDROXY, INCLUDES FRACTION(S), IF PERFORMED

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph: The correct use of an ICD-10-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.

Group 1 Codes	
ICD-10 Codes	•
E20.0	Idiopathic hypoparathyroidism
E20.8	Other hypoparathyroidism
E20.9	Hypoparathyroidism, unspecified
E21.0	Primary hyperparathyroidism
E21.1	Secondary hyperparathyroidism, not elsewhere classified
E21.2	Other hyperparathyroidism
E21.3	Hyperparathyroidism, unspecified
E55.0	Rickets, active
E55.9	Vitamin D deficiency, unspecified
E67.3	Hypervitaminosis D
E83.30	Disorder of phosphorus metabolism, unspecified
E83.31	Familial hypophosphatemia
E83.32	Hereditary vitamin D-dependent rickets (type 1) (type 2)
E83.39	Other disorders of phosphorus metabolism
E83.51	Hypocalcemia
E83.52	Hypercalcemia
E89.2	Postprocedural hypoparathyroidism
M80.00XA -	Age-related osteoporosis with current pathological fracture, unspecified site, initial encounter for
M80.88XS	fracture - Other osteoporosis with current pathological fracture, vertebra(e), sequela
M81.0	Age-related osteoporosis without current pathological fracture
M81.6	Localized osteoporosis [Lequesne]
M81.8	Other osteoporosis without current pathological fracture
M83.0	Puerperal osteomalacia
M83.1	Senile osteomalacia
M83.2	Adult osteomalacia due to malabsorption
M83.3	Adult osteomalacia due to malnutrition
M83.4	Aluminum bone disease
M83.5	Other drug-induced osteomalacia in adults
M83.8	Other adult osteomalacia
M83.9	Adult osteomalacia, unspecified
M85.80*	Other specified disorders of bone density and structure, unspecified site
M85.831*	Other specified disorders of bone density and structure, right forearm
M85.832*	Other specified disorders of bone density and structure, left forearm
M85.839*	Other specified disorders of bone density and structure, unspecified forearm
M85.851*	Other specified disorders of bone density and structure, right thigh
M85.852*	Other specified disorders of bone density and structure, left thigh
M85.859*	Other specified disorders of bone density and structure, unspecified thigh
M85.88*	Other specified disorders of bone density and structure, other site
M85.89*	Other specified disorders of bone density and structure, multiple sites
M85.9*	Disorder of bone density and structure, unspecified
M89.9*	Disorder of bone, unspecified
N18.3	Chronic kidney disease, stage 3 (moderate)
N18.4	Chronic kidney disease, stage 4 (severe)
N18.5	Chronic kidney disease, stage 5
N18.6	End stage renal disease
N25.81	Secondary hyperparathyroidism of renal origin
	al Necessity ICD-10 Codes Asterisk Explanation: **Osteopenia should be reported using ICD
	85.80, M85.831-M85.839, M89.851-M85.859, M85.88, M85.89, M85.9 or M89.9

ICD-10 Codes that DO NOT Support Medical Necessity N/A ICD-10 Additional Information

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Group 1 Codes:

General Information

Associated Information

Documentation Requirements:

The patient's medical record must contain documentation that fully supports the medical necessity for services included within this LCD. (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.

Appendices:

Not applicable

Utilization Guidelines:

Not applicable

Sources of Information and Basis for Decision

This bibliography presents those sources that were obtained during the development of this policy. National Government Services is not responsible for the continuing viability of Web site addresses listed below.

Adams J, Kantorovich V, Wu C, Javanbakt M, Hollis B. Resolution of vitamin D insufficiency in osteopenic patients results in rapid recovery of bone mineral density. *The Journal of Clinical Endocrinology and Metabolism*. 1999;84(8):2729-2730.

Autier P, Gandini S. Vitamin D supplementation and total mortality. Arch Intern Med. 2007;167(16):1730-1737.

Bischoff-Ferrari HA, Dawson-Hughs B, Willett W, et al. Effect of vitamin D on falls a meta-analysis. *JAMA*. 2004;291(16):1999-2006. www.jama.com. Accessed 03/04/2009.

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.

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*. 2005;293(18):2257-2264. www.jama.com. Accessed 03/04/2009.

Bischoff-Ferrari HA, Dawson-Hughes B, Staehelin HM, et al. Fall prevention with supplemental and active forms of vitamin D: a meta-analysis of randomized controlled trials. *BMJ.* 2009;339:b3692.

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.

Brenner: Brenner and Rector's The Kidney, 8th ed. Saunders, An imprint of Elsevier. Copyright © 2007.

Brophy Marcus M. Vitamin D tests soar as deficiency, diseases linked. USATODAY.com. Accessed 03/12/2009.

Cannell JJ. Autism and Vitamin D. *Med Hypothese*. 2008;70(4):750-759. http://www.ncbi.nlm.nih.gov/pubmed/17920208. Accessed 02/10/2009.

Cannell JJ, Hollis BW, Zasloff M, Heaney RP. Diagnosis and treatment of vitamin D deficiency. *Expert Opin Pharmacother*. 2008;9:1-12.

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*.1992;327(23):1637-1641.

Chronic Kidney Disease 2006: A Guide to Select NKF-KDOQI Guidelines and Recommendations.

Chung M, Balk EM, Brendel M, et al. Vitamin D and calcium: a systematic review of health outcomes. *Evid Rep Technol Assess.* 2009;183:1-420.

Clinical practice guidelines for bone metabolism and disease in chronic kidney disease. *American Journal of Kidney Diseases*. October 2004.

Cranney A, Horsley T, O'Donnell, et al. Effective and safetly of vitamin D in relation to bone health. AHRQ

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Publication No. 07-E013. August 2007.

Dawson-Hughes B, Harris S, Krall E, Dallal G. Effect of calcium and vitamin D supplementation on bone density in men and women 65 years of age or older. *The New England Journal of Medicine*. 1997;337(10):670-676.

Diamond T, Eisman J, Mason R, et al. Vitamin D and adult bone health in Australia and New Zealand: a position statement. *MJA*. 2005;182:6.

Disorders involving calcium, phosphorus, and magnesium. *Primary Care: Clinics in Office Practice.* 2008;35:2. W. B. Saunders Company; Copyright© 2008.

Dusso AS, Brown AJ, Slatopolsky E. Vitamin D. Am J Physiol Renal Physiol. 2005;289:F8-F28.

Gandini, S, Boniot M, Haukka J, et al. Meta-analysis of observational studies of serum 25-hydroxyvitamin D levels and colorectal, breast and prostate cancer and colorectal adenoma. *Int. J. Cancer.* 2011;128:1414-1424.

Gaugris S, Heaney RP, Boonen S, et al. Vitamin D inadequacy among post-menopausal women: a systematic review. *Q J Med*. 2005;98:667-676.

Giovannucci E. Can vitamin D reduce total mortality? Arch Intern Med. 2007;167(16):1709-1710.

Goltzman D and 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.

Hathcock J, Shao A, Vieth R, Heaney R. Risk assessment for vitamin D. Am J Clin Cutr. 2007;85:6-18.

Heaney R. Nutrition and chronic disease. Mayo Clin Proc. 2006;81(3):297-299.

Holick MF. Resurrection of vitamin D deficiency and rickets. J Clin Invest. 2006;116:2062-2072.

Holick, M. High prevalence of vitamin D inadequacy and implications for health. *Mayo Clin Proc.* 2006;81(3):353-373.

Holick M. Vitamin D Deficiency. N Engl J Med. 2007;357:266-281.

Hollis B. Vitamin D requirement during pregnancy and lactation. *Journal of Bone and Mineral Research*. 2007;V39 -V44.

Hollis B, Wagner, C. Vitamin D requirements during lactation: high-dose maternal supplementation as therapy to prevent hypovitaminosis D for both the mother and the nursing infant. 2004;80:1752s-1758s. www.ajcn.org. Accessed 02/10/09.

Jackson R, LaCroix A, Gass M, et al. Calcium plus vitamin D supplementation and the risk of fracture. *N Engl J Med*.2006;354:669-683. www.nejm.org. Accessed 02/10/2009.

Jones G, Horst R, Carter G, Makin HLG. Contemporary diagnosis and treatment of vitamin D-related disorders. *Journal of Bone and Mineral Research.* 2007;22(2):V11-V15.

Kronenberg: Williams Textbook of Endocrinology, 11th ed. Vitamin D related disorders. Saunders, An Imprint of Elsevier; Copyright © 2008. www.mdconsult.com. Accessed 10/02/2008.

Lal Y, Nair P, Lovrien F and Freeman JW. Osteomalacia presenting as pain syndromes of uncertain etiology. *S D Med.* 2009;62(5):197,199, 201.

Lappe J, Travers-Gustafson D, Davies K, Recker R, Heaney R. Vitamin D and calcium supplementation reduces cancer risk: results of a randomized trial. *Am J Clin Nutr.* 2007;85(6):1586-1591.

Lata PF, Elliott ME. Patient assessment in the diagnosis, prevention, and treatment of osteoporosis. *Nutrition in Clinical Practice*. 2007;22(3):261-275.

LeBoff M, Kohlmeier L, Hurwitz S, Franklin J, Wright J, Glowacki J. Occult vitamin D deficiency in postmenopausal US women with acute hip fracture. *JAMA*. 1999;281(16):1505-1511.

Leventis P, Patel S. Clinical aspects of vitamin D in the management of rheumatoid arthritis. *Rheumatology*. 2008;47(11):1617-1621.

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Liu PT, Stenger S, Li H, et al. Toll-like receptor triggering of a vitamin D-mediated human antimicrobial response. *Science*. 2006;311:1770-1773.

McPherson & Pincus: *Henry's Clinical Diagnosis and Management by Laboratory Methods.* 21st ed. W. B. Saunders Company; Copyright © 2006.

Metabolic bone disease in gastrointestinal illness. *Gastroenterology Clinics*. 2007;36:1. W. B. Saunders Company; Copyright © 2007.

Moe S. Disorders involving Calcium, Phosphorus and Magnesium. Prim Care Clin Office Pract. 2008;35;215-237.

Mouyis M, Ostor A, Crisp A, et al. Hypovitaminosis D among rheumatology outpatients I clinical practice. *Rheumatology* 2008;47:1349-1351.

National Institutes of Health-National Cancer Institute. (NIH-NCI). Vitamin D and Cancer Prevention: Strengths and Limits of the Evidence. http://www.cancer.gov/cancertopics/factsheet/prevention/vitamin-D. Accessed 7/19/2012.

Prince R, Austin N, Devine A, Dick I, Bruce D, Zhu K. Effects of ergocalciferol added to Calcium on the risk of falls in elderly high-risk women. *Arch Intern Med*. 2008;168(1):103-108.

Shoback D. Update in osteoporosis and metabolic bone disorders. *Journal of Clinical Endocrinology & Metabolism*. 2007;92(3):747-753. jcem.endojournals.org. Accessed 02/10/2009.

Silverberg SJ and Bilezikian JP. Primary hyperparathyroidism. In:primer on metabolic bone diseases and disorders of mineral metabolism. 7th ed. 2008;7;302-306.

Silverberg SJ, Shane E, Dempster DW, Bilezikian JP. The effects of vitamin D insufficiency in patients with primary hyperparathyroidism. *Am J Med*. 1999;107(6):561-561.

Slovik D, Adams J, Neer R, Holick M, Potts J. Deficient production of 1,25-Dihydroxyvitamin D in elderly osteoporotic patients. *The New England Journal of Medicine*. 1981;305(7):372-374.

Souberbielle JC, Body JJ, Lappe JM, et al. Vitamin D and musculoskeletal health, cardiovascular disease, autoimmunity and cancer: recommendations for clinical practice. *Autoimmunity Reviews*. 2010;9:709-715.

Vieth R, Bischoff-Ferrari H, Boucher B, et al. The urgent need to recommend an intake of vitamin D that is effective. *Am J of Clin Nutr*. 2007;85:649-650.

Wagner CL, Greer FR. Prevention of rickets and vitamin D deficiency in infants, children and adolescents. *Pediatrics* 2008;122:1142-1152. www.pediatrics.org. Assessed February 10, 2009.

Wang T, Pencina M, Booth S, et al. Vitamin D deficiency and risk of cardiovascular disease. *Circulation*. 2008;117:503-511. circ.ahajournals.org. Accessed 03/02/2009.

Wu F, Staykova T, Horne A, et al. Efficacy of an oral, 10-day course of high-dose calciferol in correcting vitamin D deficiency. *The New Zealand Medical Journal*. 2003;116(1179):1-5.

Zerwekh J. Assessment of vitamin D in population-based studies. Blood biomarkers of vitamin D status. *American Journal of Clinical Nutrition*. 2008;87(4):1087s-1091s.

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Revision History Information

Please note: Most Revision History entries effective on or before 01/24/2013 display with a Revision History Number of "R1" at the bottom of this table. However, there may be LCDs where these entries will display as a separate and distinct row.

History Date	History Number	Revision History Explanation		Change
12/01/2015	R3	An indication for hypervitaminosis D has been added to the list for "Measurement of vitamin D levels" in the Indications section of the LCD. ICD-10-CM code E67.3 has been added effective 12/01/2015	•	Request for Coverage by a Practitioner (Part B)

Reason(s) for

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Revision

Revision

Revision History Date	Revision History Number	Revision History Explanation	Re	ason(s) for Change
10/01/2015	R2	ICD-10-CM codes M85.80, M85.88 and M85.89 have been added to the "ICD-10 Codes that Support Medical Necessity" section.	•	Request for Coverage by a Practitioner (Part B) Revisions Due To ICD-10-CM Code Changes
, ,	R1	The following ICD-10-CM codes have been added: M80.00XA-M80.88XS, M85.831-M85.839, M85.851-M85.859 and ICD-10-CM code M94.9 has been removed.	•	Revisions Due To ICD-10-CM Code Changes
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Associated Documents

Attachments N/A

Related Local Coverage Documents N/A

Related National Coverage Documents N/A

Public Version(s) Updated on 12/04/2015 with effective dates 12/01/2015 - N/A <u>Updated on 10/23/2015 with effective dates 10/01/2015 - 11/30/2015 <u>Updated on 08/31/2015 with effective dates 10/01/2015 - N/A <u>Updated on 04/02/2014 with effective dates 10/01/2015 - N/A Back to Top</u></u></u>

Keywords

N/A Read the **LCD Disclaimer** Back to Top