Local Coverage Determination (LCD) for Vitamin D Assay Testing (L32132)

Contractor Information

Contractor Name	Contractor Number	Contractor Type
Noridian Administrative Services, LLC	03402	MAC - Part B

Back to Top

LCD Information

Document Information

LCD ID Number
L32132

LCD Title
Vitamin D Assay Testing

Contractor's Determination Number
J3 CB2011.01

AMA CPT/ADA CDT Copyright Statement

Primary Geographic Jurisdiction
South Dakota

Oversight Region
Region X

Original Determination Effective Date
For services performed on or after 11/14/2011

Original Determination Ending Date

Revision Effective Date
For services performed on or after 11/14/2011

Revision Ending Date

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.

Indications and Limitations of Coverage and/or Medical Necessity
Vitamin D is called a "vitamin" because of its exogenous source, predominately from oily fish in the form of vitamin D_2 and vitamin D_3. 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, CPT 82306, 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 <-2.5 or
  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 <-1.5 or
  v. Initiating bisphosphanate 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, CPT 82652, 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. 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 most clearly indicate the necessity of the test. If level <20 ng/dl or > 60 ng/dl, a subsequent level(s) may be reimbursed until the level is within the normal range.

Back to Top

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.

CPT/HCPCS Codes
GroupName
Italicized and/or quoted material is excerpted from the American Medical Association, *Current Procedural Teminology (CPT)* codes.

82306	VITAMIN D; 25 HYDROXY, INCLUDES FRACTION(S), IF PERFORMED
82652	VITAMIN D; 1, 25 DIHYDROXY, INCLUDES FRACTION(S), IF PERFORMED

ICD-9 Codes that Support Medical Necessity
The following ICD-9 CM codes support the medical necessity of CPT code 82306

252.00	HYPERPARATHYROIDISM, UNSPECIFIED
252.01	PRIMARY HYPERPARATHYROIDISM
252.02	SECONDARY HYPERPARATHYROIDISM, NON-RENAL
252.08	OTHER HYPERPARATHYROIDISM
252.1	HYPOPARATHYROIDISM
261	NUTRITIONAL MARASMUS
262	OTHER SEVERE PROTEIN-CALORIE MALNUTRITION
268.0	RICKETS ACTIVE
268.2	OSTEOMALACIA UNSPECIFIED
268.9*	UNSPECIFIED VITAMIN D DEFICIENCY
275.3	DISORDERS OF PHOSPHORUS METABOLISM

275.40*	UNSPECIFIED DISORDER OF CALCIUM METABOLISM
275.41	HYPOCALCEMIA
275.42	HYPERCALCEMIA
278.4	HYPERVITAMINOSIS D
571.9	UNSPECIFIED CHRONIC LIVER DISEASE WITHOUT ALCOHOL
579.0	CELIAC DISEASE
579.1	TROPICAL SPRUE
579.2	BLIND LOOP SYNDROME
579.3	OTHER AND UNSPECIFIED POSTSURGICAL NONABSORPTION
579.4	PANCREATIC STEATORRHEA
579.8	OTHER SPECIFIED INTESTINAL MALABSORPTION
579.9	UNSPECIFIED INTESTINAL MALABSORPTION
585.3	CHRONIC KIDNEY DISEASE, STAGE III (MODERATE)
585.4	CHRONIC KIDNEY DISEASE, STAGE IV (SEVERE)
585.5	CHRONIC KIDNEY DISEASE, STAGE V
585.6	END STAGE RENAL DISEASE
588.81	SECONDARY HYPERPARATHYROIDISM (OF RENAL ORIGIN)
733.00	OSTEOPOROSIS UNSPECIFIED
733.01	SENILE OSTEOPOROSIS
733.02	IDIOPATHIC OSTEOPOROSIS
733.09	OTHER OSTEOPOROSIS
733.90	DISORDER OF BONE AND CARTILAGE UNSPECIFIED
756.52	OSTEOPETROSIS

268.9* If more than one LCD-listed condition contributes to Vit. D deficiency in a given patient and/or is improved by Vit. D administration, coders should use: ICD-9-CM 268.9 UNSPECIFIED VITAMIN D DEFICIENCY.This code should not be used for any other indication.

275.40* Use only for HYPERCALCIURIA

The following ICD-9-CM codes support the medical necessity of CPT code 82652

268.0	RICKETS ACTIVE
268.2*	OSTEOMALACIA UNSPECIFIED
275.40*	UNSPECIFIED DISORDER OF CALCIUM METABOLISM
275.42*	HYPERCALCEMIA
592.0	CALCULUS OF KIDNEY
592.1	CALCULUS OF URETER
592.9	URINARY CALCULUS UNSPECIFIED

268.2* Use only for tumor-induced osteomalacia
275.40* Use only for unexplained hypercalciuria
275.42* Use only for unexplained hypocalcemia

Diagnoses that Support Medical Necessity
All ICD-9-CM codes listed 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 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

Back to Top

General Information

Documentations Requirements
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.

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 under Section 1862(a)(1) of the Social Security Act.

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 N/A

Utilization Guidelines

Sources of Information and Basis for Decision
IOM (Institute of Medicine). *Dietary Reference Intake for Calcium and Vitamin D*.2011. Washington D.C.: the National Academies Press

American Medical Association (AMA). Council on Science and Public Health "Appropriate Supplementation of Vitamin D," CSAPH Report 4-A-09.

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.

Bischoff-Ferrari HA, Dawson-Hughs 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.

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

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.

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.* December 1992;327:23:1637-1641.

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

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.

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

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.

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

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.]

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.

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.

Lafferty, FW. Differential diagnosis of hypercalcemia. J Bone Miner Res 1991; 6 Suppl 2:S51.

Silverberg S, Bilezikian. Primary Hyperparathyroidism. In: Primer on Metabolic Bone Diseases and Disorders of Mineral Metabolism. 7th ed., 2008:7:302-306.

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.

Am. J. Med. 107(6):561-567(1999), "The effects of vitamin D insufficiency in patients with primary hyperparathyroidism", Silverberg, S.J., et.al.

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.

Jacobus, CH, Holick, MF, Shao, Q, et al. Hypervitaminosis D associated with drinking milk. N Engl J Med 1992; 326:1173.

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.

Bernstein, CN, Leslie, WD, Leboff, MS. AGA technical review on osteoporosis in gastrointestinal diseases. Gastroenterology 2003; 124:795.

Johnson, JM, Maher, JW, Demaria, EJ, et al. The Long-term Effects of Gastric Bypass on Vitamin D Metabolism. Ann Surg 2006; 243:701.

American Gastroenterological Association medical position statement: guidelines on osteoporosis in gastrointestinal diseases. Gastroenterology 2003; 124:791.

Hahn, TJ. Drug-induced disorders of vitamin D and mineral metabolism. Clin Endocrinol Metab 1980; 9:107.

Sotaniemi, EA, Hakkarainen, HK, Puranen, JA, Lahti, RO. Radiologic bone changes and hypocalcemia with anticonvulsant therapy in epilepsy. Ann Intern Med 1972; 77:389.

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.

Compston, JE. Hepatic osteodystrophy: Vitamin D metabolism in patients with liver disease. Gut1986; 27:1073.

Holick, MF. Vitamin D deficiency. N Engl J Med 2007; 357:266.

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.

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.

Ceglia L. Vitamin D and skeletal muscle tissue and function. Mol Aspects Med. 2008 Dec;29(6):407-14. Epub 2008 Aug 8. Review.

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.

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.

Hollick MF High Prevalence of Vitamin D Inadequacy and Implications for Health Mayo Clin Proc. 2006;81(3):353-373.

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.

Ybarra J, Sánchez-Hernández J, Pérez A. Hypovitaminosis D and morbid obesity. Nurs Clin North Am. 2007 Mar;42(1):19-27, v. Review.

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.

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.

Lee JH, O'Keefe JH, Bell D et al. Vitamin D deficiency. JACC. 2008; 52(24):1949-56.

Lapp JL. Vitamin D: bone health and beyond. Am J Lifestyle Med. 2009;3:386-93.

Binkley N, Krueger D, Gemar D, Drezner MK. Correlation among 25-hydroxy-vitamin D assays. J Clin Endocrinol Metab. 2008; 93:1804–1808

Bolland MJ, Bacon CJ, Horne AM et al. Vitamin D Insufficiency and Health. Am J Clin Nutr 2010; 91:82-89.

Other Contractor(s)' Policies **Advisory Committee Meeting Notes** This draft LCD was presented at the Part A Open Door Coverage Meeting held on October 21, 2010.

This medical policy was presented at the Medicare Part B Open Public Meeting held on June 28, 2011. It was again discussed at the following Carrier Advisory Committee meetings on the following dates:

Arizona 07/12/2011
Montana 07/07/2011
North Dakota 07/19/2011
South Dakota 07/21/2011
Utah 07/14/2011
Wyoming 07/14/2011

Response to Part A Provider Recommendations from the October 21, 2010 Part A Open Door Coverage meeting draft LCD:

Comment: Providers produced literature demonstrating the dearth of evidence of the utility of Vitamin D supplementation in patients with bone loss associated with long-term steroid or anti-convulsant intake.

Response: Noridian agrees with the providers' conclusions and eliminates this coverage category.

Comment: Several commenters requested the addition of screening codes to allow for Vitamin D screening in the Medicare population.

Response: Neither Noridian nor CMS has authority to allow coverage of screening examinations. The Medicare law (Social Security Act 1862) prohibits payment for screening examinations. Congress must write specific emending legislation to allow payment for screening examinations, and such has been done for all currently covered screening, such as mammography, colonography.

Comment: Several commenters submitted literature indicating widespread prevalence of Vitamin D "deficiency" among Medicare beneficiaries and requested coverage for periodic patient examinations despite the absence of symptoms.

Response: Noridian will not add this coverage due to insufficient and questionable evidence of deficiency and benefits of treatment compounded by the absence of a reasonable understanding of the appropriate management of any deficiency in the face of known risks of supplementation. Since there is no consensus on the definition of normal and abnormal value ranges for Vitamin D, in general, but particularly among the poorly studied Medicare population; no standard across laboratories for either the assay or result reporting; and no evidence that supplementation beyond recommended daily doses is beneficial: coverage is denied. Noridian's conclusions are supported
by the November 2010 analysis of the Institute of Medicine Dietary Reference Intakes committee, a study undertaken on behalf of the USDA, DOD, FDA, HHS and NIH.

Comment: Several commenters submitted supportive literature and requested coverage for Vit. D testing in a variety of medical conditions, which may be worsened by Vit. D deficiency. These conditions include: cancer (both generally and specifically), heart disease, autoimmune disorders, especially Multiple Sclerosis, glucose homeostasis, prevention of tuberculosis, Parkinson's Disease, and overall mortality.

Response: Coverage for testing in these conditions will not be added. Vitamin D receptor sequences have been found in over 1000 genes and the literature on Vit. D has expanded exponentially over the past few years. However, all submitted and otherwise reviewed studies have produced preliminary or suggestive results requiring further study. The best randomized clinical trials are inconsistent. All reviewed systematic reviews on the other hand, including

recent AHRQ and Cochrane analyses, conclude that evidence - at best - is intriguing but not conclusive for any of the conditions. This conclusion is supported by the November 2010 analysis of the Institute of Medicine Dietary Reference Intakes committee, a study undertaken on behalf of the USDA, DOD, FDA, HHS and NIH.

Comment: One commenter requested coverage of hypovitaminosis D in the absence of symptoms or signs of disease. Another commenter requested use of condition, hypovitaminosis D, only for patients under treatment for a covered condition whose last level was low.

Response: Coverage will not be added. There is no consensus on the definition of this condition, hypovitaminosis D, or the necessity of treatment except in specific conditions as listed in this LCD. Given the lack of consensus on the normal range for Vit. D levels, especially in the Medicare population, the emerging evidence of risks of supplementation and the recommendations of Dietary Reference Intakes report against other than routine daily intake (except in the disorders listed in our LCD), there is ample reason not to add this condition.

In the case of patients on Vit. D supplementation with a need for treatment and monitoring, the underlying condition (which management is affected by Vit. D) should be coded. If more than one LCD-listed condition contributes to Vit. D deficiency in a given patient and/or is improved by Vit. D administration, coders should use: ICD-9-CM 268.9 UNSPECIFIED VITAMIN D DEFICIENCY.

Note: In this LCD, the range of "normal", for the purposes of repeat testing, was established by a consensus of Noridian providers, all experts in the fields and based on the best literature evidence currently available.

Comment: Two commenters requested the addition of Hypervitaminosis D.

Response: Noridian will add this condition. There is evidence in the literature that levels above 60 are harmful in some populations and emerging evidence of potential harm at levels lower than 60. Comment: One of the commenters requesting addition of hypervitaminosis D also requested addition of several other codes related to liver and kidney disease; malnutrition states; malaise and fatigue, myalgia and Myositis; and obesity.

Response: Severe nutritional disorders require vitamin supplementation at higher than usual levels for repletion and Noridian will add codes for both marasmus and severe protein-calorie malnutrition. The draft LCD already includes codes that specify degrees of renal disease below which one would not expect to see Vit. D abnormalities and no additional codes will be listed. The level of evidence for addition of codes for hepatic osteodystrophy, proximal myopathy, muscle strength, weight gain and obesity is C and does not support addition of the conditions to the LCD. Noridian will add a code for chronic non-alcoholic liver disease. The addition of any of the diagnoses listed here or other diagnoses depends on the submission of literature supporting the utility of Vit. D supplementation above the daily recommended levels of the Reference Dietary Intakes.

Comment: One commenter objected to the restrictions of once a year testing and one test per day.

Response: Noridian agrees and will remove the language from the LCD. Coverage for any test will be based solely on the documentation of medical necessity.

NAS Response to Provider Recommendation (for comment period ending 09/12/2011):

Comment: Two providers requested the addition of antiepileptic and glucocorticoid drug administration as an indication for Vitamin D testing.

Response: The indications will not be added. The level of evidence supporting the indication (either drug class) is C. The literature neither establishes an association between supra-normal Vit. D supplementation and any positive clinical outcome nor the consequent value of serum testing in these patients. The literature suggests that the development of osteoporosis in the setting of antiepileptic therapy is multifactorial and that supplementation with 1000 IU/day Vit. D *may* be useful. Similarly, routine supplementation with 400-800 IU Vit. D is recommended for those patients receiving glucocorticoids. (See Institute of Medicine (IOM), Dietary intake recommendations, 2011.) There is high-level evidence that administration of greater than usual doses of Vit. D in elderly women is harmful.

From the IOM Dietary intake Recommendations, 2011:

"Special Consideration

Medications. Glucocorticoids are well known for their anti-inflammatory properties. One of the most undesirable side effects of glucocorticoid therapy is severe osteopenia. One of the mechanisms by which glucocorticoids induce osteopenia is by inhibiting vitamin D-dependent intestinal calcium absorption (Lukert and Raisz, 1990). Therefore, patients on glucocorticoid therapy may require additional vitamin D in order to maintain their serum 25(OH)D levels in the mid-normal range (25 to 45 ng/ml [62.5 to 112.5 nmol/liter]).

Medications to control seizures, such as phenobarbital and dilantin, can alter the metabolism and the circulating half-life of vitamin D (Favus and Christakos, 1996). Holick (1995) recommended that patients on at least two antiseizure medications who are institutionalized, and therefore not obtaining most of their vitamin D requirement from exposure to sunlight, increase their vitamin D intake to approximately 25 µg (1,000 IU)/day to maintain their serum 25(OH)D levels within the mid-normal range of 25 to 45 ng/ml (62.5 to 112.5 nmol/liter). This should prevent the osteomalacia and vitamin D deficiency associated with antiseizure medications."

Note: During the first comment period on this LCD (Noridian Part A draft), several providers argued against our inclusion of the indications requested above and submitted literature supporting their position. Noridian agreed and removed antiepileptic and glucocorticoid drug administration as indications from the LCD. Current review of the literature supports that position.

Comment: One commenter suggested that daily recommended doses for Vit D had increased, especially for those with osteoporosis. He requested coverage of at least quarterly Vit. D testing for monitoring of these patients' Vit. D levels.

Response: Osteoporosis may be covered under the specific conditions outlined in the LCD. Recommendations for treatment are not addressed in this LCD. However, the LCD references cite routine supplementation for all adults over 50 with 400 – 1000IU daily. If there is reason to suspect an inadequate response to routine supplementation, it may be reasonable to obtain Vit. D level. Documentation must clearly identify the reason for the test and any testing frequency.

This policy does not reflect the sole opinion of the contractor or the Contractor Medical Director(s). Although the final decision rests with the contractor, this policy was developed in cooperation with the Carrier Advisory Committee(s), which include representatives of various medical specialty societies.

The Section titled "Does the 'CPT 30% Rule' apply?" needs clarification. This rule comes from the AMA (American Medical Association), the organization that holds the copyrights for all CPT codes. The rule states that if, in a given section (e.g., surgery) or subsection (e.g., surgery, integumentary) of the CPT Manual, more than 30% of the codes are listed in the LCD, then the short descriptors must be used rather than the long descriptors found in the CPT Manual.

This policy is subject to the reasonable and necessary guidelines and the limitation of liability provision.

Start Date of Comment Period 06/28/2011

End Date of Comment Period 09/12/2011

Start Date of Notice Period 11/14/2011

Revision History Number N/A

Revision History Explanation J3 CB2011.01 -
Two comments and responses will be added to the final copy in the Advisory Committee Meeting Notes under "NAS Response to Provider Recommendation (for comment period ending 09/12/2011)."

09/22/2011 - this draft LCD is being released to final.

Reason for Change

Related Documents
This LCD has no Related Documents.

LCD Attachments
There are no attachments for this LCD.

Back to Top

All Versions

Updated on 09/23/2011 with effective dates 11/14/2011 - N/A
Read the **LCD Disclaimer**
Back to Top