Local Coverage Determination (LCD) for Vitamin D Assay Testing (L31371)

Contractor Information

Contractor Name	Contractor Number	Contractor Type
Noridian Administrative Services, LLC	00320	FI

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LCD Information

Document Information

LCD ID Number
L31371

LCD Title
Vitamin D Assay Testing

Contractor's Determination Number
A2010.03 R1

AMA CPT/ADA CDT Copyright Statement

Primary Geographic Jurisdiction
Minnesota

Oversight Region
Region VIII

Original Determination Effective Date
For services performed on or after 02/08/2011

Original Determination Ending Date

Revision Effective Date
For services performed on or after 06/15/2011

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 (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.

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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.

012x	Hospital Inpatient (Medicare Part B only)
013x	Hospital Outpatient
014x	Hospital - Laboratory Services Provided to Non-patients
018x	Hospital - Swing Beds
022x	Skilled Nursing - Inpatient (Medicare Part B only)
023x	Skilled Nursing - Outpatient
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.

0300	Laboratory - General Classification
0301	Laboratory - Chemistry
0309	Laboratory - Other Laboratory

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
Conditions that are listed in the "ICD-9 Codes that Support Medical Necessity" section of this policy.

ICD-9 Codes that DO NOT Support Medical Necessity
All those not listed under the "ICD-9 Codes that Support Medical Necessity" section of this policy.

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

Diagnoses that DO NOT Support Medical Necessity

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General Information

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

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

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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.]

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

Please see the attached comment/response document link under the section "LCD Attachments". This section is found towards the bottom of the LCD.

Start Date of Comment Period 09/03/2010

End Date of Comment Period 10/28/2010

Start Date of Notice Period 12/24/2010

Revision History Number R1

Revision History Explanation Comments/Responses document is attached in section "LCD Attachments". Both the narrative under section "Indications and Limitations of Coverage and/or Medical Necessity" and the ICD-9 CM codes under section ICD-9 Codes that Support Medical Necessity " have been updated due to these comments.

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The LCD annual review was completed on 06/14/2011.

Effective 06/15/2011, the following language was added to the Documentation Requirements section of the LCD: 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.

Reason for Change CMS Requirement
Maintenance (annual review with new changes, formatting, etc.)
Narrative Change

Last Reviewed On Date 06/14/2011

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 06/23/2011 with effective dates 06/15/2011 - N/A
Updated on 12/16/2010 with effective dates 02/08/2011 - N/A
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