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

Contractor Information

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

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LCD Information

Document Information

LCD ID Number
L31371

Primary Geographic Jurisdiction
Minnesota

LCD Title
Vitamin D Assay Testing

Oversight Region
Region VIII

Contractor's Determination Number
A2010.03 R1

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

AMA CPT/ADA CDT Copyright Statement

Original Determination Ending Date
For services performed on or after 06/15/2011

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Original 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.

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.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>012x</td>
<td>Hospital Inpatient (Medicare Part B only)</td>
</tr>
<tr>
<td>013x</td>
<td>Hospital Outpatient</td>
</tr>
<tr>
<td>014x</td>
<td>Hospital - Laboratory Services Provided to Non-patients</td>
</tr>
<tr>
<td>018x</td>
<td>Hospital - Swing Beds</td>
</tr>
<tr>
<td>022x</td>
<td>Skilled Nursing - Inpatient (Medicare Part B only)</td>
</tr>
<tr>
<td>023x</td>
<td>Skilled Nursing - Outpatient</td>
</tr>
<tr>
<td>085x</td>
<td>Critical Access Hospital</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>0300</td>
<td>Laboratory - General Classification</td>
</tr>
<tr>
<td>0301</td>
<td>Laboratory - Chemistry</td>
</tr>
<tr>
<td>0309</td>
<td>Laboratory - Other Laboratory</td>
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</tbody>
</table>

CPT/HCPCS Codes

<table>
<thead>
<tr>
<th>GroupName</th>
<th>Italicized and/or quoted material is excerpted from the American Medical Association, Current Procedural Terminology (CPT) codes.</th>
</tr>
</thead>
<tbody>
<tr>
<td>82306</td>
<td>VITAMIN D; 25 HYDROXY, INCLUDES FRACTION(S), IF PERFORMED</td>
</tr>
<tr>
<td>82652</td>
<td>VITAMIN D; 1, 25 DIHYDROXY, INCLUDES FRACTION(S), IF PERFORMED</td>
</tr>
</tbody>
</table>

ICD-9 Codes that Support Medical Necessity

The following ICD-9 CM codes support the medical necessity of CPT code 82306

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>252.00</td>
<td>HYPERPARATHYROIDISM, UNSPECIFIED</td>
</tr>
<tr>
<td>252.01</td>
<td>PRIMARY HYPERPARATHYROIDISM</td>
</tr>
<tr>
<td>252.02</td>
<td>SECONDARY HYPERPARATHYROIDISM, NON-RENAL</td>
</tr>
</tbody>
</table>
### Diagnoses that Support Medical Necessity

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

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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

Documentation 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


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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.


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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.

A2010.03 R1
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
Read the LCD Disclaimer
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