# LCD Information

## Contractor Information

<table>
<thead>
<tr>
<th>CONTRACTOR NAME</th>
<th>CONTRACT TYPE</th>
<th>CONTRACT NUMBER</th>
<th>JURISDICTION</th>
<th>STATES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>02101 - MAC A</td>
<td>J - F</td>
<td>Alaska</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>02102 - MAC B</td>
<td>J - F</td>
<td>Alaska</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>02201 - MAC A</td>
<td>J - F</td>
<td>Idaho</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>02202 - MAC B</td>
<td>J - F</td>
<td>Idaho</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>02301 - MAC A</td>
<td>J - F</td>
<td>Oregon</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>02302 - MAC B</td>
<td>J - F</td>
<td>Oregon</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>02401 - MAC A</td>
<td>J - F</td>
<td>Washington</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>02402 - MAC B</td>
<td>J - F</td>
<td>Washington</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>03101 - MAC A</td>
<td>J - F</td>
<td>Arizona</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>03102 - MAC B</td>
<td>J - F</td>
<td>Arizona</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>03201 - MAC A</td>
<td>J - F</td>
<td>Montana</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>03202 - MAC B</td>
<td>J - F</td>
<td>Montana</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>03301 - MAC A</td>
<td>J - F</td>
<td>North Dakota</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>03302 - MAC B</td>
<td>J - F</td>
<td>North Dakota</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>03401 - MAC A</td>
<td>J - F</td>
<td>South Dakota</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>03402 - MAC B</td>
<td>J - F</td>
<td>South Dakota</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>03501 - MAC A</td>
<td>J - F</td>
<td>Utah</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>03502 - MAC B</td>
<td>J - F</td>
<td>Utah</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>03601 - MAC A</td>
<td>J - F</td>
<td>Wyoming</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>03602 - MAC B</td>
<td>J - F</td>
<td>Wyoming</td>
</tr>
</tbody>
</table>

## LCD Information

### Document Information

**LCD ID**
L34051

**LCD Title**
Vitamin D Assay Testing

**AMA CPT / ADA CDT / AHA NUBC Copyright Statement**

CPT codes, descriptions and other data only are copyright 2022 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply.
Proposed LCD in Comment Period
N/A

Source Proposed LCD
DL34051

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

Revision Effective Date
For services performed on or after 12/01/2019

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
12/19/2016

Notice Period End Date
02/02/2017

Issue
Issue Description

Editorial update only.

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

Created on 04/10/2023. Page 2 of 10
Vitamin D is called a "vitamin" because of its exogenous source, predominately from oily fish in the form of vitamin D \textsubscript{2} and vitamin D \textsubscript{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/ml. 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
    - T score on DEXA scan <-2.5 or
    - History of fragility fractures or
    - FRAX > 3% 10-year probability of hip fracture or 20% 10-year probability of other major osteoporotic fracture or
    - FRAX > 3% (any fracture) with T-score <-1.5 or
    - Initiating bisphosphonate therapy (Vitamin 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/ml 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/ml or > 60 ng/ml, 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


48. Other Contractor(s)' Policies.

**Bibliography**

N/A
<table>
<thead>
<tr>
<th>REVISION HISTORY DATE</th>
<th>REVISION HISTORY NUMBER</th>
<th>REVISION HISTORY EXPLANATION</th>
<th>REASONS FOR CHANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/01/2019</td>
<td>R12</td>
<td>Under Coverage Guidelines/Indications, iv. added T-score &quot;&lt;-1.5 or.&quot; Initially published in earlier versions and inadvertently removed in prior versions.</td>
<td>Typographical Error</td>
</tr>
</tbody>
</table>
| 12/01/2019            | R11                     | The following were made to the LCD due to typographical errors:  
- changing references of ng/dl to ng/ml  
- adding "<-2.5 or" in the Coverage Indications, Limitations and/or Medical Necessity section under Indications.  
- adding "<20 ng/ml or >" in the Coverage Indications, Limitations and/or Medical Necessity section under Limitations, last sentence in the last paragraph. | Typographical Error |
| 12/01/2019            | R10                     | The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.  
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. | Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD. ) |
| 12/01/2019            | R9                      | 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.  
As required by CR 10901, all billing and | Provider Education/Guidance  
Revisions Due To Code Removal |
<table>
<thead>
<tr>
<th>REVISION HISTORY DATE</th>
<th>REVISION HISTORY NUMBER</th>
<th>REVISION HISTORY EXPLANATION</th>
<th>REASONS FOR CHANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/01/2018</td>
<td>R8</td>
<td>coding information has been moved to the companion article, this article is linked to the LCD.</td>
<td></td>
</tr>
<tr>
<td>10/01/2018</td>
<td>R8</td>
<td>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. 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</td>
<td>• Revisions Due To ICD-10-CM Code Changes</td>
</tr>
<tr>
<td>02/03/2017</td>
<td>R7</td>
<td>Added ICD-10 Codes A15.0, A15.4, A15.5, A15.6, A15.7, A15.8, Z79.3, Z79.4, Z79.51, Z79.52, Z79.810, Z79.811, Z79.818, Z79.82, Z79.83, Z79.84, Z79.890, Z79.891, Z79.899</td>
<td>• Creation of Uniform LCDs Within a MAC Jurisdiction</td>
</tr>
<tr>
<td>02/03/2017</td>
<td>R6</td>
<td>Addition of codes from 2016 ICD-10 Coding updates added to Final E89.820; E89.821; E89.822; E89.823</td>
<td>• Revisions Due To ICD-10-CM Code Changes</td>
</tr>
<tr>
<td>02/03/2017</td>
<td>R5</td>
<td>This LCD version was created as a result of DL34051 being released to a Final LCD.</td>
<td>• Creation of Uniform LCDs Within a MAC Jurisdiction</td>
</tr>
<tr>
<td>10/01/2016</td>
<td>R4</td>
<td>Typographical Error</td>
<td>• Typographical Error</td>
</tr>
<tr>
<td>10/01/2015</td>
<td>R3</td>
<td>The following ICD-10 Codes were added from the ICD-10 2016-2017 update: E89820, E89821, E89822, E89823, E89824, K9041, K9049. Code K90.4 was deleted.</td>
<td>• Revisions Due To ICD-10-CM Code Changes</td>
</tr>
<tr>
<td>10/01/2015</td>
<td>R2</td>
<td>The LCD is revised to add M85.80 and M85.88 to the ICD-10 Codes that Support Medical Necessity section; CPT 82306 only.</td>
<td>• Reconsideration Request</td>
</tr>
<tr>
<td>10/01/2015</td>
<td>R1</td>
<td>This LCD is revised to remove the paragraph, “When requesting an individual consideration through the written</td>
<td>• Other (Removed the paragraph, “When requesting an individual consideration through the written</td>
</tr>
</tbody>
</table>
Redetermination (formerly appeal) process, providers must include all relevant medical records and any pertinent peer-reviewed literature that supports the request. At a minimum two (2) Phase II studies (human studies of efficacy, pivotal) or one (1) Phase III study (evidence of safety and efficacy, pivotal) must be submitted for the Medical Director’s review." from the Associated Information field.

**REVISION HISTORY**

<table>
<thead>
<tr>
<th>REVISION HISTORY DATE</th>
<th>REVISION HISTORY NUMBER</th>
<th>REVISION HISTORY EXPLANATION</th>
<th>REASONS FOR CHANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Redetermination (formerly appeal) process, providers must include all relevant medical records and any pertinent peer-reviewed literature that supports the request. At a minimum two (2) Phase II studies (human studies of efficacy, pivotal) or one (1) Phase III study (evidence of safety and efficacy, pivotal) must be submitted for the Medical Director’s review.&quot; from the Associated Information field.</td>
<td></td>
</tr>
</tbody>
</table>

**Associated Documents**

**Attachments**

N/A

**Related Local Coverage Documents**

**Articles**

- [A57719 - Billing and Coding: Vitamin D Assay Testing](#)
- [A55373 - Response to Comments: Vitamin D Assay Testing](#)

**LCDs**

- [DL34051 - (MCD Archive Site)](#)

**Related National Coverage Documents**

N/A

**Public Versions**

<table>
<thead>
<tr>
<th>UPDATED ON</th>
<th>EFFECTIVE DATES</th>
<th>STATUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>04/01/2022</td>
<td>12/01/2019 - N/A</td>
<td>Currently in Effect (This Version)</td>
</tr>
<tr>
<td>10/22/2021</td>
<td>12/01/2019 - N/A</td>
<td>Superseded</td>
</tr>
<tr>
<td>01/29/2020</td>
<td>12/01/2019 - N/A</td>
<td>Superseded</td>
</tr>
<tr>
<td>11/08/2019</td>
<td>12/01/2019 - N/A</td>
<td>Superseded</td>
</tr>
</tbody>
</table>

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

**Keywords**

N/A