

Local Coverage Determination (LCD): Vitamin D Assay Testing (L34051)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	02101 - MAC A	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02102 - MAC B	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02201 - MAC A	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02202 - MAC B	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02301 - MAC A	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02302 - MAC B	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02401 - MAC A	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	02402 - MAC B	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	03101 - MAC A	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03102 - MAC B	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03201 - MAC A	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03202 - MAC B	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03301 - MAC A	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03302 - MAC B	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03401 - MAC A	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03402 - MAC B	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03501 - MAC A	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03502 - MAC B	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03601 - MAC A	J - F	Wyoming
Noridian Healthcare Solutions, LLC	A and B MAC	03602 - MAC B	J - F	Wyoming

LCD Information

Document Information

LCD ID
L34051

Original Effective Date

For services performed on or after 10/01/2015

LCD Title

Revision Effective Date

Vitamin D Assay Testing

For services performed on or after 12/01/2019

Proposed LCD in Comment Period

N/A

Revision Ending Date

N/A

Source Proposed LCD

DL34051

Retirement Date

N/A

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Notice Period Start Date

12/19/2016

Notice Period End Date

02/02/2017

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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

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 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 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
 - 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
 - v. Initiating bisphosphonate 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 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/dl and patient is clinically stable, repeat testing is often unnecessary; if performed, documentation must clearly indicate the necessity of the test. If level 60 ng/dl, 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)**

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

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48. Other Contractor(s)' Policies.

Bibliography

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
12/01/2019	R10	<p>The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.</p> <p>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.</p>	<ul style="list-style-type: none">• Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.)
12/01/2019	R9	<p>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.</p> <p>As required by CR 10901, all billing and coding information has been moved to the companion article, this article is linked to the LCD.</p>	<ul style="list-style-type: none">• Provider Education/Guidance• Revisions Due To Code Removal
10/01/2018	R8	<p>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</p>	<ul style="list-style-type: none">• Revisions Due To ICD-10-CM Code Changes

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		<p>a restriction to the coverage determination; and, therefore not all the fields included on the Article are applicable as noted in this policy.</p> <p>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</p>	
02/03/2017	R7	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	<ul style="list-style-type: none"> • Creation of Uniform LCDs Within a MAC Jurisdiction
02/03/2017	R6	Addition of codes from 2016 ICD-10 Coding updates added to Final E89.820; E89.821; E89.822; E89.823	<ul style="list-style-type: none"> • Revisions Due To ICD-10-CM Code Changes
02/03/2017	R5	This LCD version was created as a result of DL34051 being released to a Final LCD.	<ul style="list-style-type: none"> • Creation of Uniform LCDs Within a MAC Jurisdiction
10/01/2016	R4	Typographical Error	<ul style="list-style-type: none"> • Typographical Error
10/01/2015	R3	The following ICD-10 Codes were added from the ICD-10 2016-2017 update: E89820, E89821, E89822, E89823, K9041, K9049. Code K90.4 was deleted.	<ul style="list-style-type: none"> • Revisions Due To ICD-10-CM Code Changes
10/01/2015	R2	The LCD is revised to add M85.80 and M85.88 to the ICD-10 Codes that Support Medical Necessity section; CPT 82306 only.	<ul style="list-style-type: none"> • Reconsideration Request
10/01/2015	R1	This LCD is revised to remove the paragraph, "When requesting an individual consideration through the written 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	<ul style="list-style-type: none"> • Other (Removed the paragraph, "When requesting an individual consideration through the written 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

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		(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.	of efficacy, pivotal) or one (1) Phase III study (evidence of safety and efficacy, pivotal) must be submitted for the Medical Director's review.")

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A57719 - Billing and Coding: Vitamin D Assay Testing

A55373 - Response to Comments: Vitamin D Assay Testing

LCD(s)

DL34051

- (MCD Archive Site)

Related National Coverage Documents

N/A

Public Version(s)

Updated on 01/29/2020 with effective dates 12/01/2019 - N/A

Updated on 11/08/2019 with effective dates 12/01/2019 - N/A

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Keywords

N/A