

LCD - Vitamin D Assay Testing (L37535)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
National Government Services, Inc.	MAC - Part A	06101 - MAC A	J - 06	Illinois
National Government Services, Inc.	MAC - Part B	06102 - MAC B	J - 06	Illinois
National Government Services, Inc.	MAC - Part A	06201 - MAC A	J - 06	Minnesota
National Government Services, Inc.	MAC - Part B	06202 - MAC B	J - 06	Minnesota
National Government Services, Inc.	MAC - Part A	06301 - MAC A	J - 06	Wisconsin
National Government Services, Inc.	MAC - Part B	06302 - MAC B	J - 06	Wisconsin
National Government Services, Inc.	A and B and HHH MAC	13101 - MAC A	J - K	Connecticut
National Government Services, Inc.	A and B and HHH MAC	13102 - MAC B	J - K	Connecticut
National Government Services, Inc.	A and B and HHH MAC	13201 - MAC A	J - K	New York - Entire State
National Government Services, Inc.	A and B and HHH MAC	13202 - MAC B	J - K	New York - Downstate
National Government Services, Inc.	A and B and HHH MAC	13282 - MAC B	J - K	New York - Upstate
National Government Services, Inc.	A and B and HHH MAC	13292 - MAC B	J - K	New York - Queens
National Government Services, Inc.	A and B and HHH MAC	14111 - MAC A	J - K	Maine
National Government Services, Inc.	A and B and HHH MAC	14112 - MAC B	J - K	Maine
National Government Services, Inc.	A and B and HHH MAC	14211 - MAC A	J - K	Massachusetts
National Government Services, Inc.	A and B and HHH MAC	14212 - MAC B	J - K	Massachusetts

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
National Government Services, Inc.	A and B and HHH MAC	14311 - MAC A	J - K	New Hampshire
National Government Services, Inc.	A and B and HHH MAC	14312 - MAC B	J - K	New Hampshire
National Government Services, Inc.	A and B and HHH MAC	14411 - MAC A	J - K	Rhode Island
National Government Services, Inc.	A and B and HHH MAC	14412 - MAC B	J - K	Rhode Island
National Government Services, Inc.	A and B and HHH MAC	14511 - MAC A	J - K	Vermont
National Government Services, Inc.	A and B and HHH MAC	14512 - MAC B	J - K	Vermont

LCD Information

Document Information

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LCD Title

Vitamin D Assay Testing

Proposed LCD in Comment Period

N/A

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N/A

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Notice Period Start Date

02/14/2018

Notice Period End Date

03/31/2018

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), Chapter 6, Section 20.4.3 applies 42CFR410.32 to hospitals.

Coverage Guidance**Coverage Indications, Limitations, and/or Medical Necessity**

Hypovitaminosis D may result from inadequate intake, insufficient sunlight, malabsorption, liver, kidney and genetic disease. It results in the inadequate mineralization of bone. The CDC reported approximately 300,000 hip fractures, 60,000 fall-related deaths and 33 billion dollars in health care expenditures in 2014. This LCD identifies the indications and limitations of Medicare coverage for Vitamin D; 25 hydroxy and Vitamin D; 1, 25 dihydroxy laboratory assays in the medical management of patients.

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 <-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 bisphosphonate therapy (Vitamin D level and serum calcium levels 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:

- Both assays of vitamin D need not be performed for each of the above conditions.
- 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 must clearly indicate the necessity of the test.
- If level <20 ng/ml or > 60 ng/ml are noted, a subsequent level(s) may be reimbursed until the level is within the normal range.
- Testing may not be used for routine or other screening.

Summary of Evidence

Routine use of laboratory assays to document Vitamin D deficiency remains controversial. The current United States Preventive Health Service Task Force recommendations consider current medical evidence insufficient to assess the balance of benefits and harms of screening for Vitamin D deficiency in asymptomatic adults. However, one major meta-analysis (one with five pooled randomized controlled trials including 1237 patients) concluded that Vitamin D supplementation reduced the risk of falls among ambulatory and institutionalized older individuals with stable health by more than 20%.

A second meta-analysis pooled 12 randomized controlled trials, all using cholecalciferol supplementation therapy between 700-800 IU/d. The results demonstrated a reduction in fractures of the hip of 26%, and non-vertebral fractures of 23%, in both ambulatory and institutionalized elderly persons.

There is also controversy as to the definition of vitamin D sufficiency, although many authors accept a level of 25(OH)D of at least 30 ng/ml. Accepting this metric, 25-50% of nursing home or homebound patients, greater than

50% of hospitalized patients and 30% of women with osteoporosis may still have Vitamin D deficiency despite a growing societal awareness of that deficiency as a contributing factor.

In 2009, the Agency for Healthcare Research and Quality, through the Tufts Evidenced Based Practice Center, conducted a systematic review of the scientific literature on Vitamin D and calcium intake as related to status indicators and health outcomes. This original report summarized 165 articles and 11 systematic reviews that incorporated 200 additional primary articles. In 2013, in preparation for a project in conjunction with the NIH Office of Dietary Supplements, the report was updated to include 154 new articles. Despite this effort, disagreement exists regarding Vitamin D optimum dosing, target 25(OH) vitamin D levels and the reported associations with health outcomes. Associations with cardiovascular disease, major cancers breast, prostate, colorectal and pancreatic were mixed and inconclusive. One RCT found a small effect on fall risk among older adults. As described in the original report, both the Tufts EPC and the Ottawa EPC data found good evidence that combined Vitamin D3 (200-800 IU/d) plus calcium 500mg/d supplementation resulted in a small increase in Bone Mineral Density of the spine, the total body, femoral neck and total hip.

Another AHRQ funded study, LeBlanc et al Screening for Vitamin D deficiency: A Systematic Review for the US Preventive Services Task Force (Jan. 2015) concluded that screening for Vitamin D levels in asymptomatic persons might reduce mortality risk in institutionalized elderly persons and risk for falls, but not fractures. The authors noted the inconsistency of laboratory methodology and reporting, and a lack of consensus regarding optimal 25(OH) D levels.

In its 2011 report, the Institute of Medicine shared the concerns that a "reassessment of laboratory ranges for 25-hydroxyvitamin D" was needed to decrease risks of over and under treatment of Vitamin D deficiency.

A pragmatic approach for patients and their physicians was developed by the ABIM Foundation in its Choosing Wisely initiative. The patient friendly literature reassures individuals that healthy diet and exercise maintain most persons in an adequate range of Vitamin D level. It raises the possible justification of empiric vitamin D supplementation without testing for those patients without risk factors but may be thought to have inadequate sun exposure or dietary intake, while outlining those clinical risk factors that warrant baseline diagnostic assays.

Analysis of Evidence (Rationale for Determination)

It is established that 25-hydroxyvitamin D is more reflective of total body stores of vitamin D than the shorter lived, active metabolite, 1,25 dihydroxyvitamin D. Although lack of laboratory standardization is commonly noted in most papers, it is the preferred initial assay in the evaluation of most patients with hypovitaminosis D. The 25-hydroxyvitamin D undergoes additional hydroxylation in the kidney by 1- α -hydroxylase under the influence of parathyroid hormone to produce the active metabolite. The 1,25 dihydroxyvitamin D assay is reserved for those patients where a contributory medical illness generally related to kidney disease, but also possibly related to liver, parathyroid or genetic diseases that may influence this normal metabolism.

The benefits of treatment of Vitamin D supplementation may be modest, and those benefits made difficult to quantify by general health, habits such as exercise and smoking, and other contributory factors such as ethnicity and medication treatment regimens.

However, the prevalence of osteoporosis, fall risk and skeletal fractures, and the general tolerance of the current recommended daily requirements mitigate for early supplementation in any individual uncertain regarding adequate dietary intake and sunlight exposure.

Once a beneficiary has been shown to be Vitamin D deficient, by assay or clinical findings, the correctly chosen assay

(25 hydroxyvitamin D, or 1,25 di-hydroxyvitamin D) may be used to assure correct supplementation to attain the serum levels outlined in Limitations. Continued findings outside those parameters (again outlined in the Limitations section) may warrant additional testing.

General Information

Associated Information

Sources of Information

N/A

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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
10/01/2021	R5	Language in the LCD has been corrected to indicate 20 and 50 ng/ml and <20 ng/ml or > 60 ng/ml in the "Limitations" section of the LCD.	<ul style="list-style-type: none"> • Typographical Error
11/14/2019	R4	CPT codes have been removed from the "Keywords" section of the LCD.	<ul style="list-style-type: none"> • Revisions Due To Code Removal
11/14/2019	R3	Consistent with Change Request 10901, all coding information, National coverage provisions, and Associated Information (Documentation Requirements, Utilization Guidelines) have been removed from the LCD and placed in the related Billing and Coding Article, A57736. There has been no change in coverage with this LCD revision.	<ul style="list-style-type: none"> • Revisions Due To Code Removal
10/01/2019	R2	LCD revised for annual ICD-10-CM code updates. The descriptor for ICD-10-CM code Z68.43 was changed in Group 1.	<ul style="list-style-type: none"> • Revisions Due To ICD-10-CM Code Changes
10/01/2018	R1	LCD revised for annual ICD-10-CM code updates. The descriptor for ICD-10-CM code Z68.43 was changed in Group 1.	<ul style="list-style-type: none"> • Revisions Due To ICD-10-CM Code Changes

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		<i>DATE (10/01/2018): 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.</i>	

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

[A57736 - Billing and Coding: Vitamin D Assay Testing](#)

[A55852 - Response to Comments: Vitamin D Assay Testing](#)

Related National Coverage Documents

N/A

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
09/24/2021	10/01/2021 - N/A	Currently in Effect (This Version)
01/31/2020	11/14/2019 - 09/30/2021	Superseded
11/08/2019	11/14/2019 - N/A	Superseded

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

Keywords

- Vitamin D Assay
- Osteopenia
- Bone Density