



MASSACHUSETTS

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Medical Policy

Testing Serum Vitamin D Levels

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Policy Number: 746

BCBSA Reference Number: 2.04.135

NCD/LCD: Local Coverage Determination (LCD): Vitamin D Assay Testing (L37535)

Related Policies

None

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Testing vitamin D levels in patients with signs and/or symptoms of vitamin D deficiency or toxicity may be considered **MEDICALLY NECESSARY**.

Testing vitamin D levels in asymptomatic patients may be considered **MEDICALLY NECESSARY** in the following patient populations:

- Individuals who have risk factors for vitamin D deficiency
- Institutionalized patients.

Testing vitamin D levels in asymptomatic patients is considered **NOT MEDICALLY NECESSARY** when the above criteria are not met.

“Institutionalized” as used herein refers to patients who reside at long-term facilities where some degree of medical care is provided. These circumstances and facilities can include long-term hospital stays, nursing homes, assisted living facilities, and similar environments.

There are no standardized lists of factors denoting high risk for vitamin D deficiency, and published lists of high-risk factors differ considerably. Certain factors tend to be present on most lists, however, and they may constitute a core set of factors for which there is general agreement that testing is indicated. The following list of high-risk factors was compiled from numerous sources:

- Chronic kidney disease, stage ≥ 3
- Cirrhosis/chronic liver disease
- Malabsorption states
- Osteomalacia
- Osteoporosis

- Rickets
- Hypo- or hypercalcemia
- Granulomatous diseases
- Vitamin D deficiency, on replacement
- Obstructive jaundice/biliary tract disease
- Osteogenesis imperfecta
- Osteosclerosis/osteopetrosis
- Chronic use of anticonvulsant medication or corticosteroids
- Parathyroid disorders
- Osteopenia.

Medicare HMO BlueSM and Medicare PPO BlueSM Members

Medical necessity criteria and coding guidance for **Medicare Advantage members living in Massachusetts** can be found through the link(s) below.

[Local Coverage Determinations \(LCDs\) for National Government Services, Inc.](#)

Local Coverage Determination (LCD): Vitamin D Assay Testing (L37535)

Note: To review the specific LCD, please remember to click “accept” on the CMS licensing agreement at the bottom of the CMS webpage.

For medical necessity criteria and coding guidance for **Medicare Advantage members living outside of Massachusetts**, please see the Centers for Medicare and Medicaid Services website at <https://www.cms.gov> for information regarding your specific jurisdiction.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is not required .
Commercial PPO and Indemnity	Prior authorization is not required .
Medicare HMO BlueSM	Prior authorization is not required .
Medicare PPO BlueSM	Prior authorization is not required .

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes

CPT codes:	Code Description
82306	Vitamin D; 25 hydroxy, includes fraction(s), if performed
82652	Vitamin D; 1, 25 dihydroxy, includes fraction(s), if performed

Description

Vitamin D

Vitamin D, also known as calciferol, is a fat-soluble vitamin that has a variety of physiologic effects, most prominently in calcium homeostasis and bone metabolism. In addition to the role vitamin D plays in bone metabolism, other physiologic effects include inhibition of smooth muscle proliferation, regulation of the renin-angiotensin system, a decrease in coagulation, and a decrease in inflammatory markers.¹

Vitamin D Levels

Vitamin D deficiency is best assessed by measuring serum levels of 25-hydroxyvitamin D. However, there is no consensus on the minimum vitamin D level or on the optimal serum level for overall health. A 2011 Institute of Medicine (IOM) report concluded that a serum level of 20 ng/mL is sufficient for most healthy adults.² Some experts, such as the National Osteoporosis Foundation and the American Geriatrics Society, have recommended a higher level (30 ng/mL).²

Vitamin D deficiency, as defined by suboptimal serum levels, is common in the United States. In the National Health and Nutrition Examination Survey covering the period of 2000-2004, 30% of individuals over the age of 12 had 25-hydroxyvitamin D levels less than 20 ng/mL.³ Vitamin D deficiency occurs most commonly as a result of inadequate dietary intake coupled with inadequate sun exposure. Evidence from the National Nutrition Monitoring System and the National Health and Nutrition Examination Survey has indicated that the average consumption is below recommended levels of intake. Yetley (2008) estimated that average daily intake for U.S. adults ranged from 228 to 335 IU/d, depending on gender and ethnicity.³ This level is below the average daily requirement, estimated by IOM (400 IU/d for healthy adults), and well below IOM's required daily allowance (estimated to be 600 IU for nonelderly adults and 800 IU for elderly adults).

Vitamin D deficiency may occur less commonly for other reasons. Kidney or liver disease can cause deficiency as a result of the impaired conversion of inactive vitamin D to its active products. In rare situations, there is vitamin D resistance at the tissue level, which causes a functional vitamin D deficiency despite "adequate" serum levels.

The safe upper level for serum vitamin D is also not standardized. The IOM report concluded there is potential harm associated with levels greater than 50 ng/mL and recommended that serum levels be maintained in the 20- to 40-ng/mL range.² However, conclusions on this point have differed. A 2011 Agency for Healthcare Research and Quality systematic review of vitamin D and bone health concluded that "There is little evidence from existing trials that vitamin D above current reference intakes is harmful."⁴ The Women's Health Initiative concluded that hypercalcemia and hypercalciuria in patients receiving calcium and vitamin D were not associated with adverse clinical events.⁵ The Women's Health Initiative did find a small increase in kidney stones for women ages 50 to 79 years who received vitamin D and calcium.

Associations of vitamin D levels with various aspects of health have been noted over the last several decades,^{6,7,8,9,10} and these findings have led to the question of whether supplementation improves health outcomes. For example, a relation between vitamin D levels and overall mortality has been reported in most observational studies examining this association.^{11,12} Mortality is lowest at vitamin D levels in the 25- to 40-nmol/L range. At lower levels of serum vitamin D, mortality increases steeply, and overall mortality in the lowest quintile was more than 3 times that in the middle quintiles. Theodoratou et al (2014)

identified 107 systematic reviews of observational studies examining the association between vitamin D levels and more than 100 different outcomes.¹³

Vitamin D Replacement

IOM has recommended reference values for intake of vitamin D and serum levels, based on available literature and expert consensus.² Recommended daily allowances are 600 IU/d for individuals between 1 and 70 years of age, and 800 IU/d for individuals older than 70 years.

Estimates of vitamin D requirements are complicated by the many other factors that affect serum levels. Sun exposure is the most prominent of factors that affect serum levels, and this is because individuals can meet their vitamin D needs entirely through adequate sun exposure. Other factors such as age, skin pigmentation, obesity, physical activity, and nutritional status also affect vitamin D levels and can result in variable dietary intake requirements to maintain adequate serum levels.

Excessive intake of vitamin D can be toxic. Toxic effects are usually due to hypercalcemia and may include confusion, weakness, polyuria, polydipsia, anorexia, and vomiting. In addition, high levels of vitamin D may promote calcium deposition and has the potential to exacerbate conditions such as calcium kidney stones and atherosclerotic vascular disease.

IOM defined 3 parameters of nutritional needs for vitamin D, on the assumption of minimal sun exposure. These parameters were the estimated average requirement, defined as the minimum intake required to maintain adequate levels; the recommended daily allowance, defined as the optimal dose for replacement therapy; and the upper-level intake, defined as the maximum daily dose to avoid toxicity. These recommendations are summarized in Table 1.

Table 1. Institute of Medicine Recommendations for Vitamin D Dietary Intake

Patient Group	Estimated Average Requirement, IU/d	Recommended Daily Allowance, IU/d	Upper Limit Intake, IU/d
1-3 years old	400	600	2500
4-8 years old	400	600	3000
9-70 years old	400	600	4000
>70 years old	400	800	4000

Adapted from Institute of Medicine (2011).²

Summary

Vitamin D, also known as calciferol, is a fat-soluble vitamin that has a variety of physiologic effects, most prominently in calcium homeostasis and bone metabolism. In addition to the role it plays in bone metabolism, other physiologic effects include inhibition of smooth muscle proliferation, regulation of the renin-angiotensin system, a decrease in coagulation, and a decrease in inflammatory markers.

For individuals who are asymptomatic without conditions or risk factors for which vitamin D treatment is recommended who receive testing of vitamin D levels, the evidence includes no randomized controlled trials (RCTs) of clinical utility (ie, evidence that patient care including testing vitamin D levels vs care without testing vitamin D levels improves outcomes). Relevant outcomes are overall survival, test validity, symptoms, morbid events, and treatment-related morbidity. Indirect evidence of the potential utility of testing includes many RCTs and systematic reviews of vitamin D supplementation. There is a lack of standardized vitamin D testing strategies and cutoffs for vitamin D deficiency are not standardized or evidence-based. In addition, despite the large quantity of evidence, considerable uncertainty remains about the beneficial health effects of vitamin D supplementation. Many RCTs have included participants who were not vitamin D deficient at baseline and did not stratify results by baseline 25-hydroxyvitamin D level. Nonwhite race/ethnic groups are underrepresented in RCTs but have increased risk of vitamin D deficiency. For skeletal health, there may be a small effect of vitamin D supplementation on falls, but

there does not appear to be an impact on reducing fractures for the general population. The effect on fracture reduction may be significant in elderly women, and with higher doses of vitamin D. For patients with asthma, there may be a reduction in severe exacerbations with vitamin D supplementation, but there does not appear to be an effect on other asthma outcomes. For overall mortality, there is also no benefit to the general population. RCTs evaluating extraskeletal, cancer, cardiovascular, and multiple sclerosis outcomes have not reported a statistically significant benefit for vitamin D supplementation. Although vitamin D toxicity and adverse events appear to be rare, few data on risks have been reported. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

Date	Action
2/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
3/2018	New references added from BCBSA National medical policy.
1/2017	New references added from BCBSA National medical policy.
2/2016	New medical policy describing medically necessary and not medically necessary indications. Effective 2/1/2016.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

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