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 (L33556)

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**

For procedures not listed below, please follow the above medical necessity criteria as outlined for Commercial plans.

**Indications:**
Measurement of vitamin D levels is indicated for patients with:
- Chronic kidney disease stage III or greater;
- Osteoporosis;
- Osteomalacia;
- Osteopenia;
- Hypocalcemia;
- Hypercalcemia;
- Hypoparathyroidism;
- Hyperparathyroidism;
- Hypervitaminosis D;
- Rickets; and
- Vitamin D deficiency to monitor the efficacy of replacement therapy.

**Limitations:**
For Medicare beneficiaries, screening tests are governed by statute. Vitamin D testing may not be used for routine screening.

Once a beneficiary has been shown to be vitamin D deficient, further testing is medically necessary only to ensure adequate replacement has been accomplished. Thereafter, annual testing may be appropriate depending upon the indication and other mitigating factors.

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

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

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 for information regarding your specific jurisdiction at https://www.cms.gov.

**Prior Authorization Information**
Pre-service approval is required for all inpatient services for all products. See below for situations where prior authorization may be required or may not be required. Yes indicates that prior authorization is required. No indicates that prior authorization is not required. N/A indicates that this service is primarily performed in an inpatient setting.
Outpatient

| Commercial Managed Care (HMO and POS) | No |
| Commercial PPO and Indemnity | No |
| Medicare HMO BlueSM | No |
| Medicare PPO BlueSM | No |

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:

<table>
<thead>
<tr>
<th>CPT Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT codes:</td>
</tr>
<tr>
<td>82306</td>
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<tr>
<td>82652</td>
</tr>
</tbody>
</table>

Description

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, decrease in coagulation, and decrease in inflammatory markers.

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 2010 Institute of Medicine (IOM) report concluded that a level of 20 ng/mL is sufficient for most healthy adults. Some experts, such as the National Osteoporosis Foundation and the American Geriatrics Society, recommend a higher level (30 ng/mL).

Vitamin D deficiency, as defined by suboptimal serum levels, is common in the United States. In the National Health and Nutrition Examination Survey (NHANES) survey covering the period of 2000-2004, a total of 30% of individuals over the age of 12 had 25-hydroxyvitamin D levels less than 20 ng/mL. 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 (NNMS) and the NHANES has indicated that the average consumption is below recommended levels of intake. Yetley estimated that average daily intake for U.S. adults ranged from 228 to 335 IU/d, depending on gender and ethnicity. This is below the average daily requirement, estimated by IOM (400 IU/d for healthy adults), and well below OM’s required daily allowance, which was 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 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 that 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. However, other conclusions on this point have differed. The Agency for Healthcare Research and Quality (AHRQ) systematic review on vitamin D and bone health concluded that “There is little evidence from existing trials that vitamin D above current reference intakes is harmful.” The Women’s Health Initiative (WHI) concluded that hypercalcemia and hypercalciuria in patients receiving calcium and vitamin D were not associated with adverse clinical events. The WHI did find a small increase in kidney stones for women aged 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, and these findings have led to the question of whether supplementation improves health outcomes. For example, a relationship between vitamin D levels and overall mortality has been reported in most observational studies examining this relationship. Mortality is lowest at vitamin D levels D 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.

**Vitamin D Replacement**

The IOM document recommended reference values for intake of vitamin D and serum levels, based on available literature and expert consensus. 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, 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.

On the other hand, excessive intake of vitamin D can have toxic effects. These 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. They 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>
<thead>
<tr>
<th>Patient Group</th>
<th>Estimated Average Requirement, IU/d</th>
<th>Recommended Daily Allowance, IU/d</th>
<th>Upper Limit Intake, IU/d</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-3 years old</td>
<td>400</td>
<td>600</td>
<td>2500</td>
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<tr>
<td>4-8 years old</td>
<td>400</td>
<td>600</td>
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<tr>
<td>9-70 years old</td>
<td>400</td>
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</tr>
<tr>
<td>&gt;70 years old</td>
<td>400</td>
<td>800</td>
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**Summary**

The evidence on testing vitamin D levels for skeletal health and overall mortality includes many randomized controlled trials (RCTs) and systematic reviews of vitamin D supplementation. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, symptoms, morbid events, and treatment-related morbidity. Despite the large quantity of evidence, considerable uncertainty remains regarding the beneficial health effects of vitamin D. 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,
in institutionalized individuals, and with higher doses of vitamin D. For overall mortality, there is also no benefit for the general population. Evidence from a systematic review that included trials of patients with vitamin D deficiency reported a small reduction in overall mortality for institutionalized patients. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence on the impact of vitamin D on extraskeletal health benefits, including cardiovascular disease, hypertension, diabetes, and cancer, includes many RCTs. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, symptoms, morbid events, and treatment-related morbidity. RCTs evaluating extraskeletal outcomes have not reported a benefit for vitamin D supplementation. In the available RCTs, extraskeletal outcomes were mostly secondary and occurred uncommonly. Therefore, the studies may not have had adequate power to detect a benefit, and ascertainment of outcomes may not have been optimal. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

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<thead>
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<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>1/2017</td>
<td>New references added from BCBSA National medical policy.</td>
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</table>

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

References


22. Sanders KM, Stuart AL, Williamson EJ, et al. Annual high-dose oral vitamin D and falls and fractures in older women: a randomized controlled trial. JAMA. May 12 2010;303(18):1815-1822. PMID 20460620


