Medicare Local Coverage Determination Policy

J6-NGS Vitamin D Assay Testing

CPT: 82306,82652

CMS Policy for Illinois, Michigan, Minnesota, and Wisconsin

Local policies are determined by the performing test location. This is determined by the state in which your performing laboratory resides and where your testing is commonly performed.

Medically Supportive ICD Codes are listed on subsequent page(s) of this document.

- 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 bisphosphanate 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

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- 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- alphahydroxylase 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

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Please refer to the Limitations or Utilization Guidelines section on previous page(s) for frequency information.

The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare's limited coverage policy. **If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.**

Code	Description
E55.9	
E559	Vitamin D deficiency, unspecified
Z79.899	Other long term (current) drug therapy
M81.0	Age-related osteoporosis w/o current pathological fracture
N18.31	Chronic kidney disease, stage 3a
N18.32	Chronic kidney disease, stage 3b
N18.30	Chronic kidney disease, stage 3 unspecified
M85.80	Oth disrd of bone density and structure, unspecified site
N18.4	Chronic kidney disease, stage 4 (severe)
N25.81	Secondary hyperparathyroidism of renal origin
E83.52	Hypercalcemia
E21.3	Hyperparathyroidism, unspecified
K90.9	Intestinal malabsorption, unspecified
E66.01	Morbid (severe) obesity due to excess calories
Z79.4	Long term (current) use of insulin
M81.8	Other osteoporosis without current pathological fracture
E21.0	Primary hyperparathyroidism
M85.89	Oth disrd of bone density and structure, multiple sites
M89.9	Disorder of bone, unspecified
E21.1	Secondary hyperparathyroidism, not elsewhere classified
E83.51	Hypocalcemia

Visit **QuestDiagnostics.com/MLCP** to view current limited coverage tests, reference guides, and policy information.

To view the complete policy and the full list of medically supportive codes, please refer to the CMS website reference www.cms.gov ▶

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