

Vitamin D Assay Testing

Vitamin D; 25 hydroxy

CPT: 82306

CMS Policy for Indiana and Michigan

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

Vitamin D is a hormone, synthesized by the skin, the liver, and then metabolized by the kidney to an active hormone, calcitriol. An excess of vitamin D may lead to hypercalcemia. Vitamin D deficiency may lead to a variety of disorders. This LCD identifies the indications and limitations of Medicare coverage and reimbursement for these services.

Vitamin D is called a "vitamin" because of its availability from an exogenous source, predominately from oily fish in the form of cholecalciferol, vitamin D3. Plant-based vitamin D is in the form of ergocalciferol, Vitamin D2. It is really a hormone, as it is synthesized by the skin, metabolized by the liver and converted by the kidney to an active hormone, calcitriol. Calcitriol in its classical action, absorbs calcium from the intestine, and promotes bone mineralization.

In the skin, 7-dehydrocholesterol is converted to vitamin D3 in response to sunlight, a process that is inhibited by sunscreen with a skin protection factor (SPF) of 8 or greater. Once in the blood, vitamin D2 or D3 from diet, or D3 from skin production are carried by an alpha-2-globulin, vitamin D binding protein, and are carried to the liver where they are hydroxylated to yield 25-hydroxyvitamin D (25OHD; calcidiol). 25OHD then is converted in the kidney to 1, 25(OH)2D (calcitriol) by the action of 25OHD-1-alpha hydroxylase (CYP27B1). The CYP27B1 in the kidney is regulated by nearly every hormone involved in calcium homeostasis, and its activity is stimulated by PTH, estrogen, calcitonin, prolactin, growth hormone, low calcium levels, and low phosphorus levels. Its activity is inhibited by calcitriol, thus providing the feedback loop that helps regulates its synthesis.

An excess of vitamin D is unusual, but may lead to hypercalcemia. Vitamin D deficiency may lead to a variety of disorders; the well-described is rickets in growing children or osteomalacia in adults. Evaluating the status of a patient's vitamin D sufficiency is accomplished by measuring the level of 25-hydroxyvitamin D. Measurement of other metabolites is generally not necessary outside of several unusual metabolic bone disorders or in chronic kidney disease-mineral bone disorder (CKD-MBD).

Indications

Measurement of vitamin D levels is indicated for patients with:

- chronic kidney disease stage III or greater;
- osteoporosis;
- osteomalacia;
- osteopenia;
- osteogenesis imperfecta;
- osteosclerosis;
- hypocalcemia;
- hypercalcemia;
- hypoparathyroidism;
- hyperparathyroidism;
- rickets;
- vitamin D deficiency to monitor the efficacy of replacement therapy;
- fibromyalgia;
- granuloma forming diseases;
- hypovitaminosis D;
- hypervitaminosis D;
- long term use of anticonvulsants or glucocorticoids and other medications known to lower -vitamin D levels;
- malabsorption states;
- obstructive jaundice;
- cirrhosis;
- psoriasis;
- Paget's disease of bone;
- gastric bypass.

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Limitations

For Medicare beneficiaries, screening tests are governed by statute (Social Security Act 1861 (nn)). Vitamin D testing may not be used for routine screening.

Assays of calcitriol need not be performed for each of the above conditions. The most common type of vitamin D deficiency is that of 25 OH Vitamin D.

The 1,25-dihydroxy form of vitamin D is generally only required to assist in the diagnosis of certain cases of rare endocrine disorders (primary hyperparathyroidism, hypothyroidism, pseudohypoparathyroidism), or for diagnosing and treating renal osteodystrophy and vitamin D-dependent and vitamin D resistant rickets, or in cases of unknown causes of hypercalcemia, including sarcoidosis. Level of both 25OHD and calcitriol are not needed as a panel for determining a patient's vitamin D status or to monitor routine vitamin D replacement therapy for most diseases. It is expected that the medical record will justify the tests chosen for a particular disease entity, that all available components of 25 OH vitamin D and other metabolite levels will not be performed routinely on every patient and that supportive documentation for test choices will be available to the Contractor upon request.

This Contractor does not expect to receive billing for the various component sources of 25 OH vitamin D separately (such as stored D or diet derived D). Only one total 25 OH vitamin D assay (comprising the sum of both 25OHD2 and 25OHD3) will be considered for reimbursement on any particular day, if medically necessary, for the patient's condition.

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 for this vitamin deficiency, although, generally, other parameters are measured. Annual testing of the vitamin D status may be appropriate depending upon the indication and other mitigating factors. Because there can be variability in individual 25OHD responses to supplemental vitamin D in high-risk individuals, the serum 25OHD levels could be retested after about 3 months of supplementation to confirm that the target 25OHD level has been reached. If the follow up test shows they have not yet reached the target level, the test can be repeated in another 3 months until the target level is achieved.

Testing Methods

Several methods are available for measuring circulating concentrations of 25-OH-D. Medicare will cover laboratory tests that give practitioners accurate and reliable information. The method used to perform this testing should be validated.

Utilization Guidelines

In accordance with CMS Ruling 95-1 (V. Acceptable Standards of Practice - - Application), utilization of these services should be consistent with locally acceptable standards of practice.

1. Only one 25 OH vitamin D level will be reimbursed in any 24 hour period. Storage and supplement components will not be reimbursed separately.
2. Only one 1,25-OH vitamin D level will be reimbursed in a 24 hour period if medically necessary.
3. Assays of vitamin D levels for conditions other than ICD-10 codes E55.0, E55.9, E64.3, M83.0 - M83.5, and M83.8 - M83.9 will be limited to once a year.
4. Assays of the appropriate vitamin D levels for ICD-10 codes E55.0, E55.9, E64.3, M83.0 - M83.5, and M83.8 - M83.9 will be limited to 4 per year, for the previously identified deficient form of vitamin D.

(Because there can be variability in individual 25OHD responses to supplemental vitamin D in high-risk individuals, the serum 25OHD levels could be retested after about 3 months of supplementation to confirm that the target 25OHD level has been reached. If the follow up test shows they have not yet reached the target level, the test can be repeated in another 3 months until the target level is achieved.

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There is a frequency associated with this test. Please refer to the Limitations or Utilization Guidelines section on previous page(s).

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.**

**Note—Bolded diagnoses below have the highest utilization*

Code	Description
E21.0	Primary hyperparathyroidism
E21.1	Secondary hyperparathyroidism, not elsewhere classified
E55.9	Vitamin D deficiency, unspecified
E67.2	Megavitamin-B6 syndrome
E83.32	Hereditary vitamin D-dependent rickets (type 1) (type 2)
E83.39	Other disorders of phosphorus metabolism
E83.51	Hypocalcemia
E83.52	Hypercalcemia
K90.0	Celiac disease
K90.9	Intestinal malabsorption, unspecified
M79.1	Myalgia
M79.7	Fibromyalgia
M81.0	Age-related osteoporosis without current pathological fracture
M81.8	Other osteoporosis without current pathological fracture
N18.30	Chronic kidney disease
N18.31	Chronic kidney disease
N18.32	Chronic kidney disease
N18.4	Chronic kidney disease, stage 4 (severe)
N18.5	Chronic kidney disease, stage 5
N25.81	Secondary hyperparathyroidism of renal origin
Z79.891	Long term (current) use of opiate analgesic
Z79.899	Other long term (current) drug therapy

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Disclaimer:

This diagnosis code reference guide is provided as an aid to physicians and office staff in determining when an ABN (Advance Beneficiary Notice) is necessary. Diagnosis codes must be applicable to the patient's symptoms or conditions and must be consistent with documentation in the patient's medical record. Quest Diagnostics does not recommend any diagnosis codes and will only submit diagnosis information provided to us by the ordering physician or his/her designated staff. The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

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