

## Reimbursement Policy

### Vitamin D Testing

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#### I. Policy Description

Vitamin D is a precursor to steroid hormones and plays a key role in calcium absorption and mineral metabolism. Vitamin D promotes enterocyte differentiation and the intestinal absorption of calcium. Other effects include a lesser stimulation of intestinal phosphate absorption, suppression of parathyroid hormone (PTH) release, regulation of osteoblast function, osteoclast activation, and bone resorption (Pazirandeh & Burns, 2023).

Vitamin D is present in nature in two major forms. Ergocalciferol, or vitamin D<sub>2</sub>, is found in fatty fish (e.g., salmon and tuna) and egg yolks, although very few foods naturally contain significant amounts of vitamin D. Cholecalciferol, or vitamin D<sub>3</sub>, is synthesized in the skin via exposure to ultraviolet radiation present in sunlight. Some foods are also fortified with vitamin D, most notably milk and cereals (Sahota, 2014).

Though the risk of vitamin D deficiency can differ by age, sex, and race and ethnicity, major risk factors for vitamin D deficiency include inadequate sunlight exposure, inadequate dietary intake of vitamin D-containing foods, and malabsorption syndromes, such as Crohn's disease and celiac disease (Dedeoglu et al., 2014; Looker et al., 2011).

#### II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

- 1) For individuals with an underlying disease or condition which is specifically associated with vitamin D deficiency or decreased bone density (see Note 1) or for individuals suspected of hypervitaminosis of Vitamin D, 25-hydroxyvitamin D serum testing **MEETS COVERAGE CRITERIA**.
- 2) As part of the total 25-hydroxyvitamin D analysis, testing for D<sub>2</sub> and D<sub>3</sub> fractions of 25-hydroxyvitamin D **MEETS COVERAGE CRITERIA**.

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- 3) For individuals who have documented vitamin D deficiency, repeat testing for serum 25-hydroxyvitamin D at least 12 weeks after the initiation of vitamin D supplementation therapy **MEETS COVERAGE CRITERIA** with the following restrictions:
    - a) Twice per year testing for the monitoring of supplementation therapy, until the therapeutic goal has been achieved.
    - b) Annual testing once the therapeutic range has been achieved.
  - 4) For the evaluation or treatment of conditions that are associated with defects in vitamin D metabolism (see Note 2), 1,25-dihydroxyvitamin D serum testing **MEETS COVERAGE CRITERIA**.
  - 5) The following testing **DOES NOT MEET COVERAGE CRITERIA**:
    - a) Measurement of serum 1,25-dihydroxyvitamin D to screen for vitamin D deficiency.
    - b) Routine screening for vitamin D deficiency with serum testing in asymptomatic individuals and/or during general encounters.
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### NOTES:

**Note 1:** Indications for serum measurement of 25-hydroxyvitamin D are as follows:

- A. Biliary cirrhosis and other specified disorders of the biliary tract
- B. Blind loop syndrome
- C. Celiac Disease
- D. Coronary artery disease in individuals where risk of disease progression is being considered against benefits of chronic vitamin D and calcium therapy
- E. Dermatomyositis
- F. Eating disorders
- G. Having undergone, or for those who have been scheduled for, bariatric procedures such as Roux-en-Y gastric bypass, sleeve gastrectomy, or biliopancreatic diversion with or without duodenal switch
- H. Hypercalcemia, hypocalcemia, or other disorders of calcium metabolism
- I. Hyperparathyroidism or hypoparathyroidism
- J. Individuals receiving hyperalimentation
- K. Inflammatory bowel disease (Crohn's disease and ulcerative colitis)
- L. Intestinal malabsorption
- M. Liver cirrhosis
- N. Long term use of anticonvulsants, glucocorticoids and other medications known to lower vitamin D levels
- O. Malnutrition

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- P. Myalgia and other myositis not specified
- Q. Myopathy related to endocrine diseases
- R. Neoplastic hematologic disorders
- S. Osteogenesis imperfecta
- T. Osteomalacia
- U. Osteopetrosis
- V. Osteoporosis
- W. Pancreatic steatorrhea
- X. Primary or miliary tuberculosis
- Y. Psoriasis
- Z. Regional enteritis
- AA. Renal, ureteral, or urinary calculus
- BB. Rickets
- CC. Sarcoidosis
- DD. Stage III-V Chronic Kidney Disease and End Stage Renal Disease
- EE. Systemic lupus erythematosus

**Note 2:** Indications for serum testing of 1,25-dihydroxyvitamin D are as follows:

- A. Disorders of calcium metabolism
- B. Familial hypophosphatemia
- C. Fanconi syndrome
- D. Hyperparathyroidism or hypoparathyroidism
- E. Individuals receiving hyperalimentation
- F. Neonatal hypocalcemia
- G. Osteogenesis imperfecta
- H. Osteomalacia
- I. Osteopetrosis
- J. Primary or miliary tuberculosis
- K. Renal, ureteral, or urinary calculus
- L. Rickets
- M. Sarcoidosis
- N. Stage III-V Chronic Kidney Disease and End Stage Renal Disease

### III. Applicable State and Federal Regulations

**DISCLAIMER:** If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: <https://www.cms.gov/medicare->

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[coverage-database/search.aspx](#). For the most up-to-date Medicaid policies and coverage, visit the applicable state Medicaid website.

### Food and Drug Administration (FDA)

A search of the FDA Device database on September 13, 2023, for “vitamin D” yielded 43 results. Additionally, many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). As an LDT, the U. S. Food and Drug Administration has not approved or cleared this test; however, FDA clearance or approval is not currently required for clinical use.

### IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
82306	Vitamin D; 25 hydroxy, includes fraction(s), if performed
82652	Vitamin D; 1, 25 dihydroxy, includes fraction(s), if performed
0038U	Vitamin D, 25 hydroxy D2 and D3, by LC-MS/MS, serum microsample, quantitative Proprietary test: Sensieva™ Droplet 25OH Vitamin D2/D3 Microvolume LC/MS Assay Lab/Manufacturer: InSource Diagnostics

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*Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.*

### V. Evidence-based Scientific References

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