



Vitamin D Testing

Policy MP-056 Origination Date: 06/24/2020 Reviewed/Revised Date: 05/15/2024 Next Review Date: 05/15/2025 Current Effective Date: 05/15/2024

Disclaimer:

- 1. Policies are subject to change in accordance with State and Federal notice requirements.
- 2. Policies outline coverage determinations for U of U Health Plans Commercial, CHIP and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.
- 3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
- 4. This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.

Description:

Vitamin D is a fat-soluble vitamin. Very few foods naturally contain vitamin D (fatty fish and eggs are the exception), so vitamin D is obtained primarily through fortified foods or supplements and dermal synthesis from exposure to sunlight. Vitamin D has two forms, ergocalciferol (vitamin D2) and cholecalciferol (vitamin D3), and several metabolites. Estimates of vitamin D requirements vary and depend in part upon sun exposure and the standards used to define a deficient state. It is more accurate to consider fat-soluble vitamin D as a steroid hormone, synthesized by the skin and metabolized by the kidney to an active hormone, calcitriol. Clinical disorders related to vitamin D may arise because of altered availability of the parent vitamin D, altered conversion of vitamin D to its predominant metabolites, altered organ responsiveness to hydroxylated metabolites and disturbances in the interactions of the vitamin D metabolites with PTH and calcitonin.

Policy Statement and Criteria

1. Commercial Plans/CHIP

U of U Health Plans limits coverage for vitamin D (25-OH vitamin D) testing to specific circumstances demonstrated to impact health outcomes of its members.

Circumstances in which vitamin D (25-hydroxy vitamin D testing, (CPT[®] 82306) is covered:

A. Non-pregnant individual age 18 – 64 years with any of the following:

- i. Celiac Disease
- ii. Chronic kidney disease stage III or greater
- iii. Cirrhosis/Hepatic failure
- iv. Hypocalcemia (persistent)
- v. Hypercalcemia (persistent)
- vi. Hypercalciuria (persistent)
- vii. Hypervitaminosis D
- viii. Malabsorption syndromes including:
 - a. Cystic fibrosis;
 - b. Inflammatory Bowel Disease Crohn's disease;
 - c. Bariatric surgery;
 - d. Radiation Enteritis.
 - ix. Obstructive jaundice
 - x. Osteomalacia
- xi. Osteosclerosis/petrosis
- xii. Osteoporosis if:
 - a. T score on DEXA scan; or
 - b. History of fragility fractures; or
 - c. FRAX > 3% 10-year probability of hip fracture or 20% 10-year probability of other major osteoporotic fracture; or
 - FRAX > 3% (any fracture) with T-score v. Initiating bisphosphonate therapy (Vit D level should be determined and managed as necessary before bisphosphonate is initiated).
- xiii. Rickets, acquired or congenital childhood
- xiv. Vitamin D deficiency on replacement therapy related to a condition listed above; to monitor the efficacy of treatment
- xv. Nephrolithiasis
- xvi. Hyper/hypoparathyroidism
- xvii. Chronic use of certain medications:
 - a. Antiseizure medications;
 - b. Glucocorticoids;
 - c. AIDS/HIV medications;
 - d. Antifungals, e.g. ketoconazole;
 - e. Cholestyramine.

- xviii. Granuloma-forming disorders:
 - a. Sarcoidosis;
 - b. Tuberculosis;
 - c. Histoplasmosis;
 - d. Coccidiomycosis;
 - e. Berylliosis.

Conditions for which 1, 25-OH vitamin D level (CPT[®] 82652) is covered:

- A. Unexplained hypercalcemia (suspected granulomatous disease or lymphoma);
- B. Unexplained hypercalciuria (suspected granulomatous disease or lymphoma);
- C. Suspected genetic childhood rickets;
- D. Suspected tumor-induced osteomalacia;
- E. Nephrolithiasis or hypercalciuria.

U of U Health Plans does NOT cover vitamin D testing for any other indication including screening in the general population as it is considered not medically necessary.

U of U Health Plans does NOT cover vitamin D testing (82306 or 82652 in any combination) more frequently than twice in a rolling 12-month period as it is considered not medically necessary for any diagnosis other than chronic kidney disease (CKD) or intestinal malabsorption.

U of U Health Plans does NOT cover vitamin D testing utilizing both CPT[®] 82306 and CPT[®] 82652 in combination as it is considered not medically necessary.

2. Medicaid Plans

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: <u>https://medicaid.utah.gov/utah-medicaid-official-publications/</u> or the <u>Utah Medicaid code Look-Up tool</u>

CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.

Clinical Rationale

There is a paucity of evidence evaluating the benefit and harm of testing for vitamin D. Peer-reviewed scientific literature primarily investigates the effects of vitamin D supplementation, not testing. The Washington State Health Care Authority Health Technology Assessment Program published a technology

assessment on vitamin D Screening and Testing in 2012. It was determined that no definitive conclusions can be drawn about the effectiveness of vitamin D screening or testing since no trials have been conducted to directly assess the impact of screening or testing on health outcomes, patient behavior, or clinical decision making. However, for some populations and outcomes, an association between serum levels and health outcomes and/or a positive effect of supplementation on health outcomes has been demonstrated. Thus, vitamin D screening has potential utility for identifying individuals who could benefit from the preventive or disease modifying effects of supplementation in these clinical situations when certain conditions are present or suspected to be present.

Subsequently, LeBlanc et al. in 2015 conducted a systematic review for the U.S. Preventive Services Task Force (USPSTF) to assess the benefits and harms of vitamin D screening in asymptomatic adults. The authors found "No study evaluated clinical outcomes or harms in persons screened versus not screened for vitamin D deficiency". Limited evidence in persons not known to have conditions associated with vitamin D deficiency demonstrated that treating this deficiency with vitamin D may be associated with decreased risk for death in institutionalized elderly adults and a reduction in the average number of falls but not fractures. The authors concluded that future research is needed to reduce assay variability; determine appropriate thresholds for vitamin D deficiency; and clarify effects of screening, subsequent treatment, and the subpopulations most likely to benefit. The USPSTF noted an "I" designation for this testing as routine screening outside of specific conditions being present.

Many professional societies/organizations have also provided guidance related to the proper role of vitamin D testing. These include the Endocrine Society Clinical Practice Guideline on Evaluation, Treatment, and Prevention of vitamin D Deficiency (Holick, et al., 2011) which recommends specific testing for vitamin D deficiency in individuals at risk for deficiency and do not recommend population screening for vitamin D deficiency in individuals who are not at risk. These guidelines also recommend using the serum circulating 25-hydroxyvitamin D [25(OH)D] level, measured by a reliable assay, to evaluate vitamin D status in patients who are at risk for vitamin D deficiency. As for serum 1,25dihydroxyvitamin D [1,25(OH)2D] assay these guidelines do not recommend using this testing for screening (patients at risk) and are in favor of using it only in monitoring certain conditions, such as acquired and inherited disorders of vitamin D and phosphate metabolism. The authors note there is no evidence demonstrating benefits of screening for vitamin D deficiency at a population level. Such evidence would require demonstration of the feasibility and cost-effectiveness of such a screening strategy, as well as benefits in terms of important health outcomes. In the absence of this evidence, it is premature to recommend screening at large at this time. Currently, 25(OH)D measurement is reasonable to use in groups of people at high risk for vitamin D deficiency and in whom a prompt response to optimization of vitamin D status could be expected.

The American Academy of Pediatrics (AAP) Committee on Nutrition (Golden, et al., 2014) states that evidence is insufficient to recommend universal screening for vitamin D deficiency. The AAP report advises screening for vitamin D deficiency "only in children and adolescents with conditions associated with reduced bone mass and/or recurrent low-impact fractures. More evidence is needed before recommendations can be made regarding screening of healthy black and Hispanic children or children with obesity. The recommended screening is measuring serum 25-OH-D concentration, and it is important to be sure this test is chosen instead of measurement of the 1,25-OH2-D concentration, which has little, if any, predictive value related to bone health."

Whereas the American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE) have published a Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis (Camacho, et al., 2016) which includes the following recommendation for fundamental measures concerning bone health: Measure serum 25-hydroxyvitamin D (25[OH]D) in patients who are at risk for vitamin D insufficiency, particularly those with osteoporosis (Grade B).

Several societies including the AACE/ACE, The Obesity Society, American Society for Metabolic & Bariatric Surgery (ASMBS), Obesity Medicine Association, and American Society of Anesthesiologists in 2020 provided evidence-based recommendations for Perioperative nutrition, metabolic, and nonsurgical support of patients undergoing Bariatric procedures. They recommend baseline and annual postoperative evaluation for vitamin D deficiency is recommended after Roux-en-Y gastric bypass, sleeve gastrectomy, or laparoscopic biliopancreatic diversion without or with duodenal switch (Recommendation 53) (Mechanick, 2019). The American Society for Metabolic and Bariatric Surgery (ASMBS) Integrated Health Nutritional Guidelines for the Surgical Weight Loss Patient 2016 Update: Micronutrients (Parrott, et al., 2017) specifically recommends routine pre- and post-weight loss surgery (WLS) vitamin D screening. The ASMBS states routine post-WLS screening refers to performing a nutrient assessment every 3–6 months in the first year and annually thereafter, unless otherwise specified.

As for circumstances involving primary hyperparathyroidism, Wilhelm, et al. in 2016 writing for the American Association of Endocrine Surgeons (AAES): made the recommendation to perform biochemical evaluation of suspected primary hyperparathyroidism including serum total calcium, PTH, creatinine, and 25- hydroxyvitamin D levels (strong recommendation; moderate quality evidence).

In cases of Crohn's disease the American College of Gastroenterology (ACG) recommends including "Routine laboratory investigation: Initial laboratory investigation should include evaluation for inflammation, anemia, dehydration, and malnutrition" (Lichtenstein, et al., 2018). This includes testing for 25(OH) vitamin D. The ACG also make recommendations in assessment of Primary Sclerosing Cholangitis (Lindor, et al., 2015) to screen and monitor patients with advanced liver disease should be for fat-soluble vitamin deficiencies as fat-soluble vitamin deficiencies can occur in late stages of primary sclerosing cholangitis when patient becomes jaundiced. Levels of vitamins A, E, and D should be assessed in patients with advanced disease (Conditional recommendation, moderate quality of evidence).

The ACG Clinical Guideline on the Diagnosis and Management of Celiac Disease (Rubio-Tapia, et al., 2013) recommends people with newly diagnosed celiac disease should undergo testing and treatment for micronutrient deficiencies. Deficiencies to be considered for testing should include, but not be limited to, iron, folic acid, vitamin D, and vitamin B12. (Conditional recommendation, low level of evidence).

Evidence-based guidelines from the National Osteoporosis Foundation (NOF): The NOF's Clinician's Guide to Prevention and Treatment of Osteoporosis (Cosman, et al., 2014) notes serum 25hydroxyvitamin D (25[OH]D) testing should be performed to evaluate for secondary causes of osteoporosis. It also states, "since vitamin D intakes required to correct vitamin D deficiency are so variable among individuals, serum 25(OH)D levels should be measured in patients at risk of deficiency. Vitamin D supplements should be recommended in amounts sufficient to bring the serum 25(OH)D level to approximately 30 ng/ml (75 nmol/L) and a maintenance dose recommended to maintain this level, particularly for individuals with osteoporosis. It defines vitamin D insufficiency as a serum 25-hydroxyvitamin D (25[OH]D)<30 ng/ml (75 nmol/L).

Applicable Coding CPT Codes Covered Codes

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Vitamin D; 1, 25 dihydroxy, includes fraction(s), if performed

Not Covered Codes

0038U

82652

Vitamin D, 25 hydroxy D2 and D3, by LC-MS/MS, serum microsample, quantitative

HCPCS Codes

No applicable HCPCS codes

ICD-10 Codes

A15.0-A19.9	Tuberculosis	E67.3	Hypervitaminosis D
C22.0-C22.9	Malignant neoplasm of liver and intrahepatic bile ducts	E67.8	Other specified hyperalimentation
		E68	Sequelae of hyperalimentation
C23	Malignant neoplasm of gallbladder	E83.30-E83.39	Disorders of phosphorus
C24.0-C24.9	Malignant neoplasm of other and unspecified parts of biliary tract		metabolism and phosphatases
		E83.50-E83.59	Disorders of calcium metabolism
C25.0-C25.9	Malignant neoplasm of pancreas	E84.0-E84.9	Cystic fibrosis
C26.0-C26.9	Malignant neoplasm of other and ill-defined digestive organs	E89.2	Postprocedural hypoparathyroidism
C83.80-C83.89	Other non-follicular lymphoma	К50.00-К50.919	Crohn's disease [regional enteritis]
C84.00-C84.09	Mycosis fungoides	K70.2	Alcoholic fibrosis and sclerosis of
C84.10-C84.19	Sezary disease		liver
C88.4	Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue [MALT-lymphoma]	К70.30-К70.31	Alcoholic cirrhosis of liver
		К74.0-К74.69	Fibrosis and cirrhosis of liver
D13.0-D13.9	Benign neoplasm of other and ill- defined parts of digestive system	K75.81	Nonalcoholic steatohepatitis (NASH)
D86.0-D86.89	Sarcoidosis	К76.0	Fatty (change of) liver, not elsewhere classified
E20.0	Idiopathic hypoparathyroidism	K76.89	Other specified diseases of liver
E20.8	Other hypoparathyroidism	K82.0	Obstruction of gallbladder
E20.9	Hypoparathyroidism, unspecified	K82.8	Other specified diseases of
E21.0-E21.5	Hyperparathyroidism and other disorders of parathyroid gland		gallbladder
		K82.9	Disease of gallbladder, unspecified
E24.0-E24.9	Cushing's syndrome	K83.01-K83.9	Other diseases of biliary tract
E41	Nutritional marasmus	K85.10-K85.12	Biliary acute pancreatitis
E55.0-E55.9	Vitamin D deficiency	K86.2	Cyst of pancreas
E64.3	Sequelae of rickets	K86.3	Pseudocyst of pancreas
E67.2	Megavitamin-B6 syndrome		

K86.81-K86.89	Other specified diseases of pancreas	M33.01-M33.09	Juvenile dermatomyositis
		M33.11-M33.19	Other dermatomyositis
K86.9	Disease of pancreas, unspecified	M33.91-M33.99	Dermatopolymyositis
K87	Disorders of gallbladder, biliary tract and pancreas in diseases classified elsewhere	M36.0	Dermato(poly)myositis in neoplastic disease
К90.0	Celiac Disease	M81.0-M81.8	Osteoporosis without current pathological fracture
К90.0-К90.49	Intestinal malabsorption	M83.0-M83.9	Adult osteomalacia
К90.89	Other intestinal malabsorption	M85.80-M85.9	Other specified disorders of bone
К90.9	Intestinal malabsorption, unspecified		density and structure, various sites
		M88.0-M88.9	Osteitis deformans of various sites
K91.2	Postsurgical malabsorption, not elsewhere classified	N18.3	Chronic kidney disease (CKD), stage III
L90.0	Lichen sclerosus et atrophicus	N18.4	Chronic kidney disease (CKD)
L94.0	Localized scleroderma [morphea]		stage IV
L94.1	Linear scleroderma	N18.5	Chronic kidney disease (CKD),
L94.3	Sclerodactyly		Stage V
M05.00-M05.9	Rheumatoid arthritis with rheumatoid factor	N25.81	Secondary hyperparathyroidism of renal origin
M06.00-M06.9	Other rheumatoid arthritis	Q78.0	Osteogenesis imperfecta
M32.0-M32.9	Systemic lupus erythematosus (SLE)	Q78.2	Osteopetrosis

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