

MEDICAL POLICY

SUBJECT: SCREENING FOR VITAMIN D DEFICIENCY	EFFECTIVE DATE: 08/21/14
POLICY NUMBER: 2.02.45 CATEGORY: Laboratory Test	PAGE: 1 OF: 4
<ul style="list-style-type: none">• <i>If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.</i>• <i>Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.</i>• <i>Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.</i>	

POLICY STATEMENT:

- I. Based upon our criteria and assessment of the peer-reviewed literature, screening for Vitamin D deficiency in individuals considered high risk for vitamin D deficiency (*See Policy Guideline I*) is considered **medically appropriate**.
- II. Based upon our criteria and assessment of the peer-reviewed literature, *routine* screening for Vitamin D deficiency in healthy adults or children is considered **not medically necessary**.
- III. Based upon our criteria and assessment of the peer-reviewed literature, screening for Vitamin D deficiency for non-skeletal diseases (e.g., cardiovascular disease, cancer, and autoimmune disease) is considered **not medically necessary**.

POLICY GUIDELINES:

- I. Individuals that are high risk for vitamin D deficiency include, but are not limited to:
 - A. Osteomalacia;
 - B. Osteoporosis;
 - C. Chronic kidney disease;
 - D. Hepatic failure;
 - E. Malabsorption syndromes (e.g., cystic fibrosis, inflammatory bowel disease, Crohn's disease, bariatric surgery, radiation enteritis);
 - F. Hyperparathyroidism
 - G. Medications (e.g., antiseizure, glucocorticoids, AIDS medications, antifungals, cholestyramine);
 - H. African-American and Hispanic children and adults;
 - I. Pregnant and lactating women;
 - J. Older adults (age greater than 65 years) with history of falls or nontraumatic fractures;
 - K. Obese children and adults (BMI greater than 30 kg/m²);
 - L. Granuloma-forming disorders (e.g., sarcoidosis, tuberculosis, histoplasmosis, coccidiomycosis, berylliosis);
 - M. Some lymphomas.
- II. Serum concentration of 25 hydroxyvitamin D (25OHD) is the optimal clinical indicator of vitamin D metabolism due to the rapid conversion of vitamin D to 25 OHD with only a small fraction converted to 1,25 hydroxyvitamin D (1, 25 OHD).
- III. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

A major source of vitamin D for most humans comes from exposure of the skin to sunlight typically between 1000 hours and 1500 hours in the spring, summer, and fall. Vitamin D produced in the skin may last at least twice as long in the blood compared with ingested vitamin D. A variety of factors reduce the skin's production of vitamin D₃, including increased skin pigmentation, aging, and the topical application of a sunscreen. An alteration in the zenith angle of the sun caused by a change in latitude, season of the year, or time of day dramatically influences the skin's production of

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vitamin D₃. Few foods naturally contain vitamin D₂ or vitamin D₃ however some foods have been fortified with Vitamin D.

Vitamin D deficiency results in abnormalities in calcium, phosphorus, and bone metabolism. Specifically, vitamin D deficiency causes a decrease in the efficiency of intestinal calcium and phosphorus absorption of dietary calcium and phosphorus, resulting in an increase in parathyroid hormone (PTH) levels. Secondary hyperparathyroidism maintains serum calcium in the normal range at the expense of mobilizing calcium from the skeleton and increasing phosphorus wasting in the kidneys. As a result there may be bone weakness and a generalized decrease in bone mineral density (BMD), resulting in osteopenia and osteoporosis. Vitamin D deficiency may also cause muscle weakness making standing and walking difficult for affected children. In the elderly, more frequent falls may occur, which increases their risk of fracture.

RATIONALE:

The Endocrine Society Task Force for Evaluation, Treatment and Prevention of Vitamin D deficiency (2011) recommended screening for vitamin D deficiency in individuals at risk for deficiency. The Task Force did not recommend population screening for vitamin D deficiency in individuals who are not at risk (high quality evidence). High risk for vitamin D deficiency include those individuals with osteoporosis, chronic kidney failure, malabsorption syndromes, hyperparathyroidism, African-American and Hispanic children and adults, pregnant or lactating women, older adults with history of falls or non-traumatic fractures, obese children or adults (BMI greater than 30 kg/m²), granuloma-forming disorders, and some lymphomas.

The Agency for Healthcare Research and Quality report on Vitamin D and Calcium: a systematic review of health outcomes (2009) found that no qualified systematic reviews have evaluated the association between vitamin D intake or serum 25(OH)D concentrations and incidence of cardiovascular disease, body weight in adults, total cancer incidence and mortality, immune function-related outcomes, and pregnancy. There is fair evidence between low serum 25 (OH)D levels and rickets. However no threshold level has been determined when rickets will not occur. The association between low serum 25 (OH)D levels and the risk of falls, fractures or performance measures among postmenopausal women or elderly men is inconsistent. There is fair evidence to support an association between serum 25(OH)D and BMD or changes in BMD at the femoral neck in postmenopausal women and elderly men. However more recent studies show no significant effects of vitamin D supplementation on BMD in children or adults.

The Institute of Medicine (IOM) Committee to Review Dietary Reference Intakes for Vitamin D and Calcium assessed the health outcomes associated with vitamin D and calcium (2010). The Committee found that the evidence supported a role for these nutrients in bone health but not in other health conditions. In addition, the Committee assigned an upper level to both vitamin D and calcium intake noting that beyond these levels the risk of harm increases. Too much calcium has been associated with kidney stone formation while very high levels of vitamin D are known to cause kidney and tissue damage.

The Institute for Clinical Systems Improvement (ICSI) Health Care Guidelines; Preventative Services for Adults recommendation states there is insufficient evidence to assess the balance of benefits and harms of counseling adults to get an adequate intake of vitamin D and calcium in order to prevent either cancer or bone fractures (*Weak Recommendation*). The evidence for effectiveness states that adequate calcium intake from food sources and supplements promote bone health; however, the evidence is insufficient to recommend counseling for non-institutionalized, community-dwelling, asymptomatic adults without previous history of fractures or cancer. However, vitamin D supplementation does appear to be effective in preventing injury from falls in community-dwelling adults aged 65 years and over who are at increased risk for falls.

The U.S. Preventative Task Force (USPSTF) guidelines for Vitamin D and Calcium Supplementation to Prevent Fractures (2013) concluded that the current evidence is insufficient to assess the balance of the benefits and harms of combined vitamin D and calcium supplementation for the primary prevention of fractures in premenopausal women or in men (Grade I statement). In addition the current evidence is insufficient to assess the balance of the benefits and harms of daily supplementation with greater than 400 IU of vitamin D₃ and greater than 1,000 mg of calcium for the primary prevention of fractures in non-institutionalized postmenopausal women (Grade I statement). The USPSTF

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recommends against daily supplementation with 400 IU or less of vitamin D₃ and 1,000 mg or less of calcium for the primary prevention of fractures in non-institutionalized postmenopausal women. (Grade: D Recommendation).

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT: 82306 Vitamin D; 25 hydroxy, includes fraction(s), if performed
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HCPCS: No specific code(s)

ICD9: 252.00-252.1 Disorders of the parathyroid gland (code range)
268.0 Rickets, active
268.2 Osteomalacia, unspecified
268.9 Unspecified vitamin D deficiency
275.3 Disorders of phosphorus metabolism
275.41 Hypocalcemia
275.42 Hypercalcemia
585.3-585.6 Chronic kidney disease, Stage III to End stage renal disease (code range)
588.81 Secondary hyperparathyroidism (of renal origin)
733.00 Osteoporosis, unspecified
733.01 Senile osteoporosis
733.02 Idiopathic osteoporosis
733.03 Disuse osteoporosis
733.09 Other, osteoporosis
733.90 Disorder of bone and cartilage, unspecified

ICD10: E20.0 Idiopathic hypoparathyroidism
E20.8 Other hypoparathyroidism
E20.9 Hypoparathyroidism, unspecified
EE21.3 Hyperparathyroidism, unspecified
E55.0 Rickets, active
E55.9 Vitamin D deficiency, unspecified
E83.3-83.9 Disorders of phosphorus metabolism (code range)
E83.51 Hypocalcemia
E83.52 Hypercalcemia
M81.0 Age-related osteoporosis without current pathological fracture
M81.6 Localized osteoporosis

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M81.8	Other osteoporosis without current pathological fracture
M83.0-M83.9	Adult osteomalacia (code range)
M85.9	Disorder of bone density and structure, unspecified
N18.3-N18.5	Chronic kidney disease, Stage III to End stage renal disease (code range)
N25.81	Secondary hyperparathyroidism of renal origin

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KEY WORDS:

Vitamin D, 25(OH) vitamin D

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) for Vitamin D Assay Testing. Please refer to the following LCD website for Medicare Members: [http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=29510&ContrId=181&ver=35&ContrVer=1&CtrctrSelected=181*1&Ctrctr=181&name=National+Government+Services%2c+Inc.+\(13202%2c+MAC+-+Part+B\)&s=41&DocType=All&bc=AggAAIAAAAAAA%3d%3d&](http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=29510&ContrId=181&ver=35&ContrVer=1&CtrctrSelected=181*1&Ctrctr=181&name=National+Government+Services%2c+Inc.+(13202%2c+MAC+-+Part+B)&s=41&DocType=All&bc=AggAAIAAAAAAA%3d%3d&)