MEDICAL POLICY

Excellus

SUBJECT: SCREENING FOR VITAMIN D DEFICIENCY	EFFECTIVE DATE: 08/21/14 REVISED DATE: 04/16/15, 06/16/16, 07/20/17, 07/19/18
POLICY NUMBER: 2.02.45 CATEGORY: Laboratory Test	PAGE: 1 OF: 5

- ***If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.***
- ***If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.***
- ***If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.***

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 who are high risk for vitamin D deficiency include, but are not limited to the those with following conditions:
   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/m^2);
   L. Granuloma-forming disorders (e.g., sarcoidosis, tuberculosis, histoplamosis, 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 D_3, 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

vitamin D_3. Few foods naturally contain vitamin D_2 or vitamin D_3 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, malabsoprtion 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/m^2), granuloma-forming disorders, and some lymphomas.

The Agency for Healthcare Research and Quality (AHRQ) 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. In a 2014 updated report, the AHRQ found solid agreement with the findings of the original report, the majority of the findings concerning vitamin D, alone or in combination with calcium, on the health outcomes of interest were inconsistent. Associations observed in prospective cohort and nested case-control studies were inconsistent, or when consistent, were rarely supported by the results of randomized controlled trials. Although a large number of new studies (and longer followups to older studies) were identified, particularly for cardiovascular outcomes, all-cause mortality, several types of cancer, and intermediate outcomes for bone health, no firm conclusions can be drawn. Studies identified for the current report suggest a possible U-shaped association between serum 25(OH)D concentrations and both all-cause mortality and hypertension and also suggest that the level of supplemental vitamin D and calcium administered in the Women's Health Initiative Calcium-Vitamin D Trial are not associated with an increased risk for cardiovascular disease or cancer among postmenopausal women who are not taking additional supplemental vitamin D and calcium. Studies suggest the method used to assay 25(OH)D may influence the outcomes of dose-response assessments. Beyond these observations, it is difficult to make any substantive statements on the basis of the available evidence concerning the association of either serum 25(OH)D concentration, vitamin D supplementation, calcium intake, or the combination of both nutrients, with the various health outcomes because most of the findings were inconsistent.

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, Calcium, or Combined Supplementation for the Primary Prevention of Fractures in Community-Dwelling Adults was updated in April 2018. The Task Force concluded the current evidence is insufficient to assess the balance of the benefits and harms of vitamin D and calcium supplementation, alone or combined, for the primary prevention of fractures in men and premenopausal women(Grade: I Recommendation). The current evidence is insufficient to assess the balance of the benefits and harms of daily supplementation with doses greater than 400 IU of vitamin D and greater than 1000 mg of calcium for the primary prevention of fractures in community-dwelling, postmenopausal women (Grade: I Recommendation).The USPSTF recommends against daily supplementation with 400 IU or less of vitamin D and 1000 mg or less of calcium for the primary prevention of fractures in community-dwelling, postmenopausal women Grade: D Recommendation).

The U.S. Preventative Task Force (USPSTF) guidelines for Screening for Vitamin D deficiency in adults: U.S. Preventive Services Task Force Recommendation Statement (2015) found no studies that evaluated the direct benefit of screening for vitamin D deficiency in adults. The Task Force found adequate evidence that the harms of treatment of vitamin D deficiency are small to none. No studies reported on the harms of treatment of vitamin D deficiency or identified a significant increase in total adverse events, hypercalcemia, kidney stones, or gastrointestinal symptoms. The Task Force found adequate evidence that treatment of asymptomatic vitamin D deficiency has no benefit on cancer, type 2 diabetes mellitus, risk for death in community-dwelling adults, and risk for fractures in persons not selected on the basis of being at high risk for fractures. The Task Force found inadequate evidence on the benefit of treatment of asymptomatic vitamin D deficiency on other outcomes, including psychosocial and physical functioning. Although the evidence is adequate for a few limited outcomes, the overall evidence on the early treatment of asymptomatic, screen-detected vitamin D deficiency in adults to improve overall health outcomes is inadequate. The USPSTF concluded that the evidence on screening for vitamin D deficiency in community-dwelling, nonpregnant, asymptomatic adults aged 18 years or older to improve health outcomes is insufficient and that the balance of benefits and harms of screening and early intervention cannot be determined.

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
	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 (e.g., SensievaTM Droplet 25OH Vitamin D2/D3 Microvolume LC/MS Assay *effective* 4/1/18)

HCPCS:	No specific code(s)	
ICD10:	E20.0	Idiopathic hypoparathyroidism
	E20.8	Other hypoparathyroidism

E20.9	Hypoparathyroidism, unspecified
E21.0 -E21.3	Hyperparathyroidism and other disorders of parathyroid gland (code range)
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
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: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37535&ContrId=298&ver=5&ContrVer=1&CntrctrSelected=298*1&Cntrctr=298&s=41&DocType=Active&bc=AAgAAAQAAAAA&