

Clinical UM Guideline

Subject:	Screening for Vitamin D Deficiency in Average Risk Individuals	Publish Date:	10/01/2024
Guideline #:	CG-LAB-11	Last Review Date:	08/08/2024
Status:	Reviewed		

Description

This document addresses routine testing of serum vitamin D levels in adults and children, in the absence of clinical signs and symptoms of vitamin D deficiency or intoxication or conditions for which vitamin D supplementation may be recommended. Vitamin D testing is a non-invasive blood test which can aid in the identification and clinical management of individuals at-risk for vitamin D deficiency. This document does not address testing for vitamin D in individuals who exhibit clinical manifestations or risk factors of vitamin D deficiency or toxicity.

Clinical Indications

Not Medically Necessary:

Testing vitamin D levels in individuals with no known signs or symptoms of vitamin D deficiency or intoxication nor conditions for which vitamin D treatment is recommended is considered **not medically necessary**.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Not Medically Necessary:

When the code describes a procedure specified in the Clinical Indications section as not medically necessary.

CPT

82306	Vitamin D; 25 hydroxy, includes fraction(s), if performed [when specified as screening]
82652	Vitamin D; 1, 25 dihydroxy, includes fraction(s), if performed [when specified as screening]
0038U	Vitamin D, 25 hydroxy D2 and D3, by LCMS/MS, serum microsample, quantitative Sensieva™ Droplet 25OH Vitamin D2/D3 Microvolume LC/MS Assay; InSource Diagnostics

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ICD-10 Diagnosis

	Including, but not limited to the following:
Z00.00	Encounter for general adult medical examination without abnormal findings
Z00.129	Encounter for routine child health examination without abnormal findings
Z01.419	Encounter for gynecological examination (general) (routine) without abnormal findings

Discussion/General Information

Vitamin D is normally an endogenously produced, fat-soluble vitamin; endogenous synthesis is prompted by ultraviolet rays on the skin which triggers synthesis of this essential vitamin. Vitamin D is naturally present in a limited number of foods and is available as a dietary supplement. Whether obtained from food, supplements, or exposure to ultraviolet rays, vitamin D must undergo further synthesis in the liver and kidneys to be converted from an inert form to an activated form useful for the body's vital functions, aiding functions in calcium absorption for bone strengthening, modulation of cell growth, and neuromuscular and immune functions. Due to the complexity in the synthesis of vitamin D, there is misunderstanding in the medical community regarding the best indicators for vitamin D deficiency. For instance, measurement of 1,25-dihydroxyvitamin, or calcitriol (produced by the kidneys), is commonplace for vitamin D deficiency testing; however, it is a poor indicator due to its efficient regulation by other vitamin and hormone levels as well as its relatively short half-life (15 hours). Generally, calcitriol levels do not decrease markedly unless an individual has a severe deficiency in vitamin D. Conversely, serum measurement of 25-hydroxyvitamin D, or calcidiol (produced by the liver), is a much more reliable indicator of vitamin D status. Although levels of calcidiol also do not correlate significantly with Vitamin D stores, it is a reflection of serum circulating levels of cutaneously produced and ingested vitamin D with a half-life averaging 15 days. Unfortunately, there is considerable disagreement regarding the serum levels of calcidiol (25-hydroxyvitamin D) that are indicative of deficiency warranting intervention, such as dietary supplementation. Further complicating medical management of Vitamin D deficiency, is the wide variability that exists in laboratory analysis methods. There are also health risks associated with excessive vitamin D levels and vitamin D toxicity, such as anorexia, weight loss, polyuria, kidney stones, and heart arrhythmias. Toxicity is most likely to result from over-supplementation (National Institutes of Health [NIH], 2016).

Despite the uncertainty that remains in clinical practice regarding not only the clinical benefit of vitamin D serum testing, but even the definition of vitamin D deficiency, screening of asymptomatic, average-risk individuals (e.g., non-pregnant, community dwelling adults without osteoporosis or chronic kidney disease), remains commonplace. A study evaluating data from the National Ambulatory Medical Care Survey and the National Hospital Ambulatory Medical Care Survey found that diagnosis for vitamin D deficiency more than tripled between 2008 and 2010 (383 in 2008 vs. 1177 visits per 100,000 population in 2010) (Huang, 2014).

The U.S. Preventive Services Task Force (USPSTF) has rated the current medical evidence insufficient to assess the balance of benefits and harms of screening for vitamin D deficiency in asymptomatic adults. This recommendation is specified to be applicable to "community-dwelling, non-pregnant adults aged 18 years or older

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who are seen in primary care settings and are not known to have signs or symptoms of vitamin D deficiency or conditions for which vitamin D treatment is recommended” (USPSTF, 2021).

The Endocrine Society published clinical practice guideline recommendations in 2011, which contain the following statement related to screening for vitamin D deficiency in both children and adults, “We recommend screening for vitamin D deficiency in individuals at risk for deficiency. We do not recommend population screening for vitamin D deficiency in individuals who are not at risk.” This recommendation is based on the Endocrine Society’s highest level of evidence and the rating denoted as ‘strong’, meaning the Task Force has confidence that individuals who receive care according to the recommendation “will derive, on average, more good than harm” (Holick, 2011).

The American Society of Clinical Pathology (ASCP, 2020) contributed the following recommendation to Choosing Wisely®:

Vitamin D deficiency is common in many populations, particularly in patients at higher latitudes, during winter months and in those with limited sun exposure. Over the counter Vitamin D supplements and increased summer sun exposure are sufficient for most otherwise healthy patients. Laboratory testing is appropriate in higher risk patients when results will be used to institute more aggressive therapy (e.g., osteoporosis, chronic kidney disease, malabsorption, some infections, obese individuals).

In 2024 the Endocrine Society published clinical practice guidelines on vitamin D for the prevention of disease. Regarding testing for vitamin D deficiency, the convened panel developed the following consensus statement: “Based on the absence of supportive clinical trial evidence, the panel suggests against routine 25(OH)D testing in the absence of established indications.” This recommendation applies to every age group (Demay, 2024).

No FDA labeled indications exist for measuring serum concentrations of hydroxylated to yield 25-hydroxyvitamin D (25-OH-D [i.e., vitamin D testing]). According to the Centers for Medicare & Medicaid Services (CMS) Local Coverage Determinations (LCDs) L33996, L37535, L34051, L36692, L39391 and L34658 titled, *Vitamin D Assay Testing*, “Vitamin D testing may not be used for routine screening.” As stated above, several nationally recognized clinical practice guidelines address appropriate clinical scenarios for vitamin D testing, none recommend testing for routine screening.

In summary, there are a number of conditions, some of which are aforementioned, that would place individuals at risk for development of vitamin D deficiency and merit testing of vitamin D levels for screening and management. According to the Endocrine Society’s (Holick, 2011) recommendations, infants who may be at risk for vitamin D deficiency include those who are breast-fed without vitamin D supplementation, have darker pigmented skin, and those with maternal vitamin D deficiency. Adults may be at higher risk for vitamin D deficiency if their outdoor activities are greatly limited (for example, those who are institutionalized or the elderly), if they practice aggressive sun protection measures or if living in an area considered high risk. Pregnancy, lactation, obesity and certain medication regimens are additional circumstances that may place individuals at high risk for vitamin D deficiency and may warrant screening, supplementation and on-going clinical management. However, based on the current

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evidence and consensus recommendations, screening for vitamin D deficiency in average-risk, asymptomatic adults and children, is not recommended.

Definitions

Endogenous: To be produced or synthesized within an organism or system.

Screening: Examination of a group to separate well persons from those who have an undiagnosed pathologic condition or who are at high risk.

References**Peer Reviewed Publications:**

1. Huang KE, Milliron BJ, Davis SA, Feldman SR. Surge in US outpatient vitamin D deficiency diagnoses: National Ambulatory Medical Care Survey analysis. *South Med J*. 2014; 107(4):214-217.
2. LeBlanc ES, Zakher B, Daeges M, et al. Screening for vitamin D deficiency: a systematic review for the U.S. Preventive Services Task Force. *Ann Intern Med*. 2015; 162(2):109-122.
3. Rockwell M, Kraak V, Hulver M, Epling J. Clinical management of low vitamin D: a scoping review of physicians' practices. *Nutrients*. 2018. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5946278/>. Accessed on July 14, 2024.
4. Yayla Ç, Kurek M, Turan I, et al. Association between maternal circulating 25 hydroxyvitamin D concentration and placental volume in the first trimester. *J Matern Fetal Neonatal Med*. 2017; 30(24):2944-2950.

Government Agency, Medical Society, and Other Authoritative Publications:

1. American Society for Clinical Pathology. Choosing Wisely: Fifteen things physicians and patients should question. Updated September 2020. Available at: https://www.ascp.org/content/docs/default-source/get-involved-pdfs/istp_choosingwisely/ascp-35-things-list_2020_final.pdf. Accessed on July 14, 2024.
2. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD): MoIDX: Vitamind D Assay Testing.
 - LCD L33996. Available at: <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33996&ver=30&keyword=vitamin%20d&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1>. Accessed on July 18, 2024.
 - LCD L3735. Available at: <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=37535&ver=18&keyword=vitamin%20d&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1>. Accessed on July 18, 2024.
 - LCD L34051. Available at: <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34051&ver=42&keyword=vitamin%20d&keywordType=starts&areaId=all>

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- LCD L36692. Available at: <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=36692&ver=26&keyword=vitamin%20d&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1>. Accessed on July 18, 2024.
 - LCD L34658. Available at: <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34658&ver=34&keyword=vitamin%20d&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1>. Accessed on July 18, 2024.
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3. Demay MB, Pittas AG, Bikle DD, et al. Vitamin D for the Prevention of Disease: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2024 Jun 3 [Epub ahead of print].
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 5. Holick MF, Binkley NC, Bischoff-Ferrari HA, et al. Evaluation, treatment, and prevention of vitamin D deficiency: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2011; 96(7):1911-1130.
 6. Kahwati LC, LeBlanc E, Weber RP, et al. Screening for Vitamin D Deficiency in Adults: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force. JAMA. 2021; 325(14):1443-1463.
 7. US Preventive Services Task Force, Krist AH, Davidson KW, et al. Screening for Vitamin D Deficiency in Adults: US Preventive Services Task Force Recommendation Statement. JAMA. 2021; 325(14):1436-1442.

Websites for Additional Information

1. National Institutes of Health (NIH) Office of Dietary Supplements. Vitamin D: Fact sheet for health professionals. Updated on June 02, 2022. Available at: <https://ods.od.nih.gov/factsheets/VitaminD-HealthProfessional/>. Accessed on July 18, 2024.

History

Status	Date	Action
Reviewed	08/08/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised Discussion/General Information, Background/Overview, References, and Websites for Additional Information.

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Reviewed	08/10/2023	MPTAC review. Updated Background/Overview and References sections.
Reviewed	08/11/2022	MPTAC review. Updated References section.
Reviewed	08/12/2021	MPTAC review. Updated Discussion/General Information and References section.
Reviewed	08/13/2020	MPTAC review. Updated References section and reformatted Coding section.
Reviewed	08/22/2019	MPTAC review. Updated Discussion/General Information and References sections.
Reviewed	09/13/2018	MPTAC review. Updated Discussion/General Information and References sections.
	03/29/2018	Updated Coding section with 04/01/2018 CPT PLA changes; added 0038U.
Reviewed	11/02/2017	MPTAC review. Updated header language from “Current Effective Date” to “Publish Date.” Updated Discussion/General Information section.
New	09/13/2017	MPTAC review. Initial document development.

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