Vitamin D Testing

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➲ Instructions for Use

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Related Policies
None

Coverage Rationale

Overview

Vitamin D deficiencies are the result of dietary inadequacy, impaired absorption and use, increased requirement, or increased excretion. Vitamin D deficiency can occur when usual intake is lower than recommended levels over a period of time or when exposure to sunlight is limited. Vitamin D deficiency can also result from the inability of the kidneys to convert the Vitamin D to its active form.

CMS National Coverage Determinations (NCDs)

Medicare does not have an NCD for Vitamin D Testing.

CMS Local Coverage Determinations (LCDs) and Articles

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Vitamin D Testing.

For coverage guidelines for states/territories with no LCDs/LCAs, refer to the coverage rationale below.

For Medicare, screening tests are governed by statute (Social Security Act 1861 {nn}). Vitamin D testing may not be used for routine screening.

Vitamin D testing is considered reasonable and necessary for a condition or medical diagnosis associated with Vitamin D deficiency or risk of hypercalcemia; refer to the *Vitamin D Testing: Diagnosis Codes* list under the Applicable Codes section.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service; however, language may be included in the listing below to indicate if a code is non-covered. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
82652	Vitamin D; 1, 25 dihydroxy, includes fraction(s), if performed

Diagnosis Codes
Vitamin D Testing: Diagnosis Codes

Centers for Medicare and Medicaid Services (CMS) Related Documents

After checking the table below and searching the Medicare Coverage Database, if no NCD, LCD, or LCA is found, refer to the criteria as noted in the Coverage Rationale section above.

NCD	LCD	LCA	Contractor Type	Contractor Name
CPT 82652				
N/A	L37535 Vitamin D Assay Testing	A57736 Billing and Coding: Vitamin D Assay Testing	Part A and B	NGS
N/A	L36692 Vitamin D Assay Testing	A57718 Billing and Coding: Vitamin D Assay Testing	Part A and B	Noridian
N/A	L34051 Vitamin D Assay Testing	A57719 Billing and Coding: Vitamin D Assay Testing	Part A and B	Noridian
N/A	L34658 Vitamin D Assay Testing	A57484 Billing and Coding: Vitamin D Assay Testing	Part A and B	WPS*
N/A	L34914 Assays for Vitamins and Metabolic Function	A56416 Billing and Coding: Assays for Vitamins and Metabolic Function	Part A and B	Novitas**

Medicare Administrative Contractor (MAC) With Corresponding States/Territories	
MAC Name (Abbreviation)	**States/Territories**
CGS Administrators, LLC (CGS)	KY, OH
First Coast Service Options, Inc. (First Coast)	FL, PR, VI
National Government Services, Inc. (NGS)	CT, IL, ME, MA, MN, NH, NY, RI, VT, WI
Noridian Healthcare Solutions, LLC (Noridian)	AS, AK, AZ, CA, GU, HI, ID, MT, NV, ND, Northern Mariana Islands, OR, SD, UT, WA, WY
Novitas Solutions, Inc. (Novitas)	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX, VA**
Palmetto GBA (Palmetto)	AL, GA, NC, SC, TN, VA**, WV
Wisconsin Physicians Service Insurance Corporation (WPS)*	IA, IN, KS, MI, MO, NE
Notes	
*Wisconsin Physicians Service Insurance Corporation: Contract Number 05901 applies only to WPS Legacy Mutual of Omaha MAC A Providers. **For the state of Virginia: Part B services for the city of Alexandria and the counties of Arlington and Fairfax are excluded for the Palmetto GBA jurisdiction and included within the Novitas Solutions, Inc. jurisdiction.	

Clinical Evidence

In a retrospective cohort study of patients in a tertiary care hospital, Amjad et al. (2021) studied the predictors of mortality in gastroparesis and determined nutritional deficiencies. Out of 320 patients, the authors found 48.8% had vitamin D deficiency and that advanced age, coronary artery disease (CAD), chronic kidney disease (CKD), COPD and malnutrition were all associated with higher mortality in gastroparesis for both diabetic and nondiabetic patients. It was also found that nutritional counseling was underutilized.

Bischoff-Ferrari, et al. (2020) conducted the DO-HEALTH study which investigated whether vitamin D, omega-3s and a strength training program (provided alone or in combination) improved the health outcomes of older individuals. A total of

1,075 participants were randomized into one of eight groups: 1) Vitamin D, omega-3s and strength-training exercise, 2) Vitamin D and omega-3s, 3) Vitamin D and strength-training exercise, 4) Vitamin D, 5) omega-3s and strength-training exercise, 6) omega-3s, 7) strength-training exercise and 8) placebo. Trial software was responsible for the randomization, blinding, treatment allocation and study labeling. Participants received 2 capsules per day which included either Vitamin D or placebo and omega-3s or placebo; all capsules had a coating to prevent unblinding. The strength exercise program which consisted of 30 minutes 3 times/week were provided by a physiotherapist not involved in the program. Primary outcomes were measured for cardiovascular, bone, muscle, brain and immune system health. Participants were followed for 3 years with annual clinical visits and telephone calls every 3 months to collect appropriate information. The overall withdrawal rate across all groups was almost 12%. After analysis, the authors concluded a treatment of vitamin D, omega-3s and strength exercise did not result in a statistically significant difference in improvement of BP, physical performance, infection rates, cognitive function or nonvertebral fractures. Study limitations included 83% of participants already engaged in a moderate to high physical exercise program thus there may have been little benefit from the added exercise, the overall improvement in cognitive function might be explained by a learning effect, 40% of participants were allowed to take an additional 800 IU/d of supplemental vitamin D outside of what was dispensed to them per current guidelines and the P value may have been too liberal given the large number of randomization groups and comparisons.

De Boer et al. (2019) conducted a randomized controlled trial over 5 years to assess whether supplementation with vitamin D3 or omega-3 fatty acids prevents development or progression of chronic kidney disease (CKD) in type 2 diabetes patients. 1,312 adults with type 2 diabetes were randomized into one of four groups: (1) vitamin D plus omega-3 fatty acids; (2) vitamin D plus placebo omega-3 fatty acids; (3) omega-3 fatty acids plus placebo vitamin D; or (4) both placebos. Blood and urine samples were collected by mail prior to randomization (for baseline) and again at 2 and 5 years. In addition, at baseline and year 2, serum 25(OH)D concentrations and the plasma omega-3 index (EPA plus DHA as a percentage of total fatty acids) were measured by liquid chromatography–tandem mass spectrometry. The primary outcome of this study was a change in the estimated glomerular filtration rate (GFR) from baseline to year 5. For vitamin D supplementation (or matching placebo), 92% of participants were compliant for the first 2 years and 88% were compliant at 5 years; for omega-3 fatty acids supplementation (or matching placebo) that were taken, 91% of patients were compliant at 2 years and 89% were compliant through year 5. Two years post randomization, mean serum 25(OH)D concentrations were 41.4ng/mL for participants assigned to vitamin D and 29.8 ng/mL for participants assigned to the vitamin D placebo. Mean omega-3 indexes were 3.6% for participants assigned to omega-3 fatty acids and 2.3% for participants assigned to the omega-3 fatty acid placebo. The authors found supplementation with vitamin D3 or omega-3 fatty acids, compared with placebo, resulted in no significant difference between the groups.

In a meta-analysis, Gupta et al. (2019) evaluated the potential role of vitamin D and its analogues as a therapy for diabetic nephropathy. A literature search of PubMed, Scopus, Google scholar identified 9 RCTs for analysis. The studies included 734 patients (369 patients who received vitamin D and 365 who received placebo). The primary outcomes measured were percent change in urine albumin creatine ratio (UACR), change in urinary albumin excretion rate (UAER), change in 24-hour urine protein excretion and urine protein creatinine index. Secondary outcomes included changes in levels of calcium, serum creatinine, PTH, 25 (OH) vitamin D and 1.25 (OH) vitamin D. The authors analysis demonstrated a significant increase in 25 (OH) vitamin D levels without a significant increase in serum calcium in the intervention group suggesting vitamin D may be safe to use in diabetic nephropathy. Limitations included a variation in the overall quality of the studies included as the studies varied in their design, methodology, duration of intervention and primary outcome measure, lack of RCTs methodology and blinding and lack of long-term follow-up.

Lemieux et al. (2019) conducted a randomized, double-blind, placebo-controlled, parallel-group trial on 96 patients with diagnosis of high risk diabetes or newly diagnosed type 2 diabetes. For six months one group (n = 48) received a daily dose of vitamin D3 5000 IU and the other group (n = 48) received the placebo. The objective was to determine if vitamin D supplementation improved insulin sensitivity. All participants were instructed to continue with their usual diet and exercise habits throughout the study. The primary endpoint was a change in peripheral insulin sensitivity which was measured by M-valve (using a 2-h hyper insulinemic-euglycemic clamp). Participants were given the same set of instructions 24 hours before the M—valve measurement at baseline and 6 months: eat the same dinner the night before the clamp, avoid any physical activity (except walking), and avoid alcohol and caffeine for 24h prior to the procedure. The International Physical Activity Questionnaire (IPAQ, 2005) was used to assess physical activity and a web-based, food frequency questionnaire was administered to evaluate daily energy, vitamin D and calcium intakes both at baseline and at the end of the study. Compliance was similar in both groups with the treatment group at 93.2% and the control group at 88.6%; five patients withdrew early in the study citing personal reasons and/or the experience of side effects. The data showed after 6 months, serum 25(OH) D increased by a mean of 79.1nmol/L in the treatment group and did not change in the placebo group. The authors found supplementation of vitamin D over 6 months significantly improved peripheral insulin sensitivity. Limitations included small sample size, Caucasian participants only which restricted the generalizability to other ethnic groups, and the mean baseline serum was higher than expected in about half the participants. Another RCT placebo-controlled trial (Gagnon et al. 2014) which supplied a daily dose of calcium carbonate (1,200 mg) and cholecalciferol over 6 months

found no improvement in insulin sensitivity for patients with risk of type 2 diabetes, however the authors did find there may be a benefit of treatment on insulin sensitivity in participants with prediabetes.

There is limited evidence showing population-based screening for vitamin D deficiency improves healthcare outcomes, but some specific interventions like the electronic health record (EHR) have been shown to help decrease unnecessary screening. Through a committee-based process, Petrilli, et al. (2018) developed a point of care advisory EHR alert system that was triggered whenever a vitamin D test was ordered. When the test was ordered, an electronic chart alert was initiated that provided reasons to the healthcare worker why the test should not be ordered and to only do so if the patient was high risk. After 3 months of implementation, a significant decline in the order of tests was observed. Over a 3-year period, both low value and appropriate tests continued to decline. The authors findings suggested that a health care system can have positive effects on reducing unnecessary testing and screening through education along with support from an EHR.

Shallis et al. (2017) conducted a cohort review of 54 patients, all having some type of Non-Hodkins Lymphoma but over 50% of them with diffuse large B-cell lymphoma. Hypercalcemia was defined as a value > 10.5 g/dL. Of the 54 cases, 31 blood samples collected identified serum calcitriol and 24 were for serum PTHrP level. Seven of the 31 patients had an elevated serum calcitriol level; out of 24 patients only 3 had an elevated serum PTHrP level. Approximately 30% of the original 54 patients had both the serum PTHrP and calcitriol levels measured; of these 17 patients that had measurement of both the serum calcitriol and PTHrP levels, most had neither an elevated serum calcitriol nor elevation in the serum PTHrP. The remaining 7 patients identified 5 patients with an elevated calcitriol level and 2 had an elevated PTHrP level. No patient had an elevation of both values. Upon analysis of the information, the authors concluded patients with calcitriol-mediated hypercalcemia showed a trend toward worse outcomes, suggesting that calcitriol might be a marker of high-grade lymphoma or a substitute for more advanced disease. Limitations included small sample size and retrospective review which may have contributed to bias.

Williams et al. (2021) conducted a study that aimed to assess whether supplementing the participants with Vitamin D improved their irritable bowel syndrome (IBS) symptoms. 135 people were randomized into two group; one group received a daily sublingual flavored liquid spray that delivered 3,000 IU of vitamin D3, and the other group a placebo. Vitamin D was measured as 25(OH) vitamin D2 and 25(OH) vitamin D3 using blood collected from a fingerprick; samples were obtained at baseline and again at 3 months. IBS symptoms were evaluated every two weeks throughout the trial using an IBS symptom severity questionnaire. The survey contained questions that addressed both severity and duration of abdominal pain, abdominal distension, satisfaction with bowel habits and general well-being. The authors found no benefit of vitamin D supplementation on either symptoms of IBS or the participants quality of life; however, with the prevalence of vitamin D deficiency in this population, routine screening and supplementation should be implemented for general health reasons.

Clinical Practice Guidelines

American Geriatrics Society

In a consensus statement from the American Geriatrics Society, the overall goal for primary care practitioners is to reduce falls and fall-related injuries for the aging population. The minimum goal for older adults should be a serum 25(OH)D concentration of 30 ng/mL (75 nmol/L). The AGS states laboratory testing for serum 25(OH)D concentration is not necessary before supplementation begins and there is no need to “clinically manage” vitamin D with repeated lab tests (American Geriatrics Society (AGS), 2014).

The American Society for Metabolic and Bariatric Surgery (ASMBS)

For weight loss surgery (pre- and post-surgery), the ASMBS recommends nutrient screening for vitamin D and calcium however more research is needed to establish a recommendation regarding the use of vitamin D binding protein assays as an additional tool for determining vitamin D status in post-WLS patients (Parrott, 2017).

American Society for Clinical Pathology (ASCP)

The ASCP in partnership with American Board of Internal Medicine (ABIM) Foundation states many individuals do not need a vitamin D test because it does not improve treatment for the individual. While many people have low vitamin D levels, they are not seriously low and simple dietary changes are sufficient enough to get the necessary amount of vitamin D needed.

Endocrine Society

The Endocrine Society only recommends vitamin D screening for those individuals who might be at risk for vitamin D deficiency; there is not sufficient evidence to recommend screening individuals who are not at risk (Holick, 2011).

National Institute for Health and Care Excellence (NICE)

Guidance from NICE (updated in 2017) states routine Vitamin D tests are not needed for individuals unless they have symptoms of deficiency, are considered to be at high risk for deficiency, or there is a clinical reason to do so (e.g., osteomalacia).

National Kidney Foundation

The 2020 update to the Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guideline for Nutrition in chronic kidney disease (CKD) makes the following recommendations and statements:

For vitamin D supplementation for vitamin D deficiency and insufficiency:

- In adults with CKD 1-5D (2C) or posttransplantation (OPINION), we suggest prescribing vitamin D supplementation in the form of cholecalciferol or ergocalciferol to correct 25-hydroxyvitamin D (25(OH)D) deficiency/insufficiency.
- In adults with CKD 1-5 with nephrotic range proteinuria, it is reasonable to consider supplementation of cholecalciferol, ergocalciferol, or other safe and effective 25(OH)D precursors (OPINION).

For total calcium intake:

- In adults with CKD 3-4 not taking active vitamin D analogs, we suggest that a total elemental calcium intake of 800-1,000 mg/d (including dietary calcium, calcium supplementation and calcium-based phosphate binders) be prescribed to maintain a neutral calcium balance (2B).
- In adults with CKD 5D, it is reasonable to adjust calcium intake (dietary calcium, calcium supplements, or calcium-based binders) with consideration of concurrent use of vitamin D analogs and calcimimetics in order to avoid hypercalcemia or calcium overload (OPINION).
  (Ikizler et al., 2020)

U.S. Preventive Services Task Force (USPSTF)

To update its 2014 recommendation, the U.S. Preventive Services Task Force (USPSTF) commissioned a systematic review on screening for vitamin D deficiency, including the benefits and harms of screening and early treatment. The conclusion was that the current evidence is insufficient to assess the balance of benefits and harms of screening for vitamin D deficiency in asymptomatic adults (USPSTF, 2021, Kahwati 2021).

U.S. Food and Drug Administration (FDA)

Vitamin D screening is a laboratory test and not managed by the FDA.

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Policy History/Revision Information

Date	Summary of Changes
10/01/2024	**Centers for Medicare & Medicaid (CMS) Related Documents** • Added notation for the state of Virginia to indicate "Part B services for the city of Alexandria and the counties of Arlington and Fairfax are excluded for the Palmetto GBA jurisdiction and included within the Novitas Solutions, Inc. jurisdiction"

09/01/2024	**Template Update**
	• Reformatted and reorganized policy; transferred content to new template
	• Changed policy type classification from "Policy Guideline" to "Medical Policy"
	• Added *Clinical Evidence*, *FDA*, and *References* sections
	• Updated *Instructions for Use*
	• Removed *Questions and Answers (Q&A)* section
	Related Policies
	• Removed reference link to the UnitedHealthcare Medicare Advantage Policy Guideline titled *Clinical Diagnostic Laboratory Services*
	Coverage Rationale
	• Replaced coverage indications and limitations with language to indicate:
	  ○ Medicare does not have a National Coverage Determination (NCD) for vitamin D testing
	  ○ Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable; for specific LCDs/LCAs, refer to the table [in the *Centers for Medicare & Medicaid (CMS) Related Documents* section of the policy]
	  ○ For coverage guidelines for states/territories with no LCDs/LCAs, refer to the coverage rationale below:
	  ▪ For Medicare, screening tests are governed by statute *(Social Security Act 1861 {nn})*
	  ▪ Vitamin D testing may not be used for routine screening
	  ▪ Vitamin D testing is considered reasonable and necessary for a condition or medical diagnosis associated with vitamin D deficiency or risk of hypercalcemia; refer to the *Vitamin D Testing: Diagnosis Code List* in the *Applicable Codes* section [of the policy]
	Applicable Codes
	• Removed CPT code 82306
	• Removed list of applicable ICD-10 diagnosis codes for CPT code 82306
	Centers for Medicare and Medicaid Services (CMS) Related Documents
	• Updated list of documents available in the *Medicare Coverage Database* to reflect the most current information
	• Added list of applicable *Medicare Administrative Contractors (MACs) With Corresponding States/Territories*

Date	Summary of Changes
	• Added notation to indicate the Wisconsin Physicians Service Insurance Company (WPS) Contract Number 05901 applies only to WPS Legacy Mutual of Omaha MAC A Providers **Supporting Information** • Archived previous policy version MPG377.09

Instructions for Use

The Medicare Advantage Policy documents are generally used to support UnitedHealthcare coverage decisions. It is expected providers retain or have access to appropriate documentation when requested to support coverage. This document may be used as a guide to help determine applicable:

- Medical necessity coverage guidelines; including documentation requirements, and/or
- Medicare coding or billing requirements.

Medicare Advantage Policies are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates. This Policy is provided for informational purposes and does not constitute medical advice. It is intended to serve only as a general reference and is not intended to address every aspect of a clinical situation. Physicians and patients should not rely on this information in making health care decisions. Physicians and patients must exercise their independent clinical discretion and judgment in determining care. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes this policy. For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.

Medicare Advantage Policies are developed as needed, are regularly reviewed, and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policies at any time by publishing a new version on this website. Medicare source materials used to develop these policies may include, but are not limited to, CMS statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and manuals. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. The information presented in this Policy is believed to be accurate and current as of the date of publication. Where there is a conflict between this document and Medicare source materials, the Medicare source materials apply. Medicare Advantage Policies are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

UnitedHealthcare follows Medicare coverage guidelines found in statutes, regulations, NCDs, and LCDs to determine coverage. The clinical coverage criteria governing certain items or services referenced in this Medical Policy have not been fully established in applicable Medicare guidelines because there is an absence of any applicable Medicare statutes, regulations, NCDs, or LCDs setting forth coverage criteria and/or the applicable NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD. As a result, in these circumstances, UnitedHealthcare applies internal coverage criteria as referenced in this Medical Policy. The internal coverage criteria in this Medical Policy was developed through an evaluation of the current relevant clinical evidence in acceptable clinical literature and/or widely used treatment guidelines. UnitedHealthcare evaluated the evidence to determine whether it was of sufficient quality to support a finding that the items or services discussed in the policy might, under certain circumstances, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Providers are responsible for submission of accurate claims. Medicare Advantage Policies are intended to ensure that coverage decisions are made accurately. UnitedHealthcare Medicare Advantage Policies use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

For members in UnitedHealthcare Medicare Advantage plans where a delegate manages utilization management and prior authorization requirements, the delegate's requirements need to be followed.