

Vitamin D Assay Testing

MEDICAL POLICY NUMBER: 94

Effective Date: 4/1/2024	COVERAGE CRITERIA	2
Last Review Date: 2/2023	POLICY CROSS REFERENCES.....	3
Next Annual Review: 2/2025	POLICY GUIDELINES.....	4
	REGULATORY STATUS.....	4
	CLINICAL EVIDENCE AND LITERATURE REVIEW	4
	BILLING GUIDELINES AND CODING	6
	REFERENCES.....	7
	POLICY REVISION HISTORY.....	8

INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

Commercial

Medicaid/OHP*

Medicare**

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**Medicare Members

This Company policy may be applied to Medicare Plan members only when directed by a separate Medicare policy. Note that investigational services are considered “**not medically necessary**” for Medicare members.

COVERAGE CRITERIA

Initial Testing

- I. Measurement of 25-hydroxyvitamin D level [25(OH)D], CPT Code 82306, may be considered **medically necessary** for patients with **any** of the following conditions (A.-N.):
 - A. Chronic kidney disease stage III or greater
 - B. Cirrhosis
 - C. Hypocalcemia
 - D. Hypercalcemia
 - E. Hypercalciuria
 - F. Hypervitaminosis D
 - G. Parathyroid disorders
 - H. Malabsorption states
 - I. Obstructive jaundice
 - J. Osteomalacia
 - K. Osteoporosis if (1.-5.):
 1. T score on DEXA scan $<-2/5$; **or**
 2. History of fragility fractures; **or**
 3. FRAX $> 3\%$ 10-year probability of hip fracture or 20% 10-year probability of other major osteoporotic fracture; **or**
 4. FRAX $>3\%$ (any fracture) with T-score **or**
 5. Initiating bisphosphonate therapy (vitamin D level should be determined and managed as necessary before bisphosphonate is initiated)
 - L. Osteosclerosis/petrosis
 - M. Rickets

N. Vitamin D deficiency on replacement therapy related to a condition listed above; to monitor the efficacy of treatment.

NOTE: Please refer to the LCD L34051 for the complete list of ICD-10 codes for indications in which 25-hydroxyvitamin D level [25(OH)D], CPT Code 82306, may be considered medically necessary.¹

II. Measurement of 25-hydroxyvitamin D level [25(OH)D], CPT Code 82306, is considered **not medically necessary** for diagnosis codes not listed in the Group 1 code table in the LCD L34051.

III. Measurement of 1,25-dihydroxyvitamin D[1,25(OH)2D], CPT code 82652, level may be considered **medically necessary** for patients with **any** of the following conditions (A.-E.):

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

Note: Please refer to the LCD L34051 for the complete list of ICD-10 codes for indications in which 1,25-dihydroxyvitamin D[1,25(OH)2D], CPT code 82652, may be considered medically necessary.¹

IV. Measurement of 1,25-dihydroxyvitamin D[1,25(OH)2D], CPT code 82652, is considered **not medically necessary** for diagnosis codes not listed in the Group 2 code table in the LCD L34051.¹

Repeat Testing

V. Repeat measurement of 25(OH)D or D[1,25(OH)2D] may be considered **medically necessary** to ensure adequate vitamin D replacement has been accomplished if initial testing results in levels <20 ng/ml (50 nmol/liter).

VI. Repeat measurement of 25(OH)D or D[1,25(OH)2D] may be considered **medically necessary** if level <20 ng/ml or > 60 ng/ml, a subsequent level(s) may be reimbursed until the level is within the normal range.

VII. Repeat measurement of 25(OH)D or D[1,25(OH)2D] is considered **not medically necessary** if vitamin D level is between 20 and 50 ng/ml and patient is clinically stable. (If performed, documentation must clearly indicate the necessity of the test.)

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be [accessed here](#).

POLICY GUIDELINES

This policy may be primarily based on the following Center for Medicare and Medicaid Services (CMS) guidance resources:

- Local Coverage Determination (LCD): Vitamin D Assay Testing (L34051)¹
- Local Coverage Article: Billing and Coding: Vitamin D Assay Testing (A57719)²

BACKGROUND

Vitamin D is called a "vitamin" because of its exogenous source, predominately from oily fish in the form of vitamin D2 and vitamin D3. 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 dihydroxylated metabolites and disturbances in the interactions of the vitamin D metabolites with PTH and calcitonin. Normal levels of vitamin D range from 20 – 50 ng/ml.

The most common type of vitamin D deficiency is 25-OH vitamin D. A much smaller percentage of 1,25-dihydroxy vitamin D deficiency exists; mostly, in those with renal disease. Although it is not the active form of the hormone, 25-OH vitamin D is much more commonly measured because it better reflects the sum total of vitamin D produced endogenously and absorbed from the diet than does the level of the active hormone 1, 25 -dihydroxy vitamin D. Deficiency of 1,25-dihydroxy vitamin D, which is present at much lower concentrations, does not necessarily reflect deficiency of 25-OH vitamin D and its measurement should be limited to the indications listed above.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

CLINICAL EVIDENCE AND LITERATURE REVIEW

CLINICAL PRACTICE GUIDELINES

Note: The following major U.S. medical associations provided feedback during the response period for the LCD:

- American Clinical Laboratory Association (ACLA)
- College of American Pathology (CAP)

- Endocrine Society

Noridian responded by publishing a related Local Coverage Article (LCA) A55373: Response to Comments: Vitamin D Assay Testing, and adjusted the LCD language where appropriate.³

Below are current clinical practice guidelines on Vitamin D testing that are not cited in the LCD, but support the criteria above.

U.S. Preventive Services Task Force (USPSTF)

In 2021, the USPSTF published evidence-based clinical practice guidelines regarding the efficacy of vitamin D screening in adults, which recommended the following:⁴

“The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for vitamin D deficiency in asymptomatic adults.”

American Society of Clinical Pathology (ASCP)

In 2013, the ASCP contributed the following recommendation to Choosing Wisely®:⁵

“Don’t perform population based screening for 25-OH-Vitamin D deficiency.

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).”

Endocrine Society

In 2013, the Endocrine Society contributed the following recommendation to Choosing Wisely®.⁶

“Don’t routinely measure 1,25-dihydroxyvitamin D unless the patient has hypercalcemia or decreased kidney function.

Because 1,25-dihydroxyvitamin D is the active form of vitamin D, many practitioners think that measuring 1,25-dihydroxyvitamin D is an accurate means to estimate vitamin D stores and test for vitamin D deficiency, which is incorrect... Serum 25-hydroxyvitamin D levels may be overused, but when trying to assess vitamin D stores or diagnose vitamin D deficiency (or toxicity), 25-hydroxyvitamin D is the correct test.”

The 2011 Endocrine Society evidence-based clinical practice guideline on the evaluation, treatment, and prevention of vitamin D deficiency recommended the following regarding vitamin D testing:⁷

- “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.”

The taskforce stated that individuals at risk of “currently, 25(OH)D measurement is reasonable 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 guidelines list several indications in which screening would be reasonable.

- “We 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. Vitamin D deficiency is defined as a 25(OH)D below 20 ng/ml (50 nmol/liter)... We recommend against using the serum 1,25-dihydroxyvitamin D [1,25(OH)2D] assay for this purpose and are in favor of using it only in monitoring certain conditions, such as acquired and inherited disorders of vitamin D and phosphate metabolism.”

Both of these strong recommendations were based on high-quality evidence, consisting of “well-performed RCTs or exceptionally strong evidence from unbiased observational studies.”

National Institute for Health and Care Excellence

In 2022, the NICE published guidelines addressing the management of multiple sclerosis in adults. Authors recommended against using vitamin B12 injections to treat multiple sclerosis.⁸

EVIDENCE SUMMARY

There is insufficient evidence that Vitamin D testing in healthy, asymptomatic individuals or for conditions not specifically associated with vitamin D deficiency improves health outcomes. There are no evidence-based clinical practice guidelines that recommend routine vitamin D testing for screening of asymptomatic individuals or for the treatment of multiple sclerosis. Furthermore, the United States Preventive Services Task Force (USPSTF) guidelines, do not recommend routine screening for vitamin D deficiency due to insufficient evidence of clinical utility.

BILLING GUIDELINES AND CODING

For a list of ICD-10 codes that are considered medically necessary for codes 82306 and 82652, please refer to the following Centers for Medicare & Medicaid Services documents:

- Local Coverage Determination (LCD): Vitamin D Assay Testing (L34051)¹
- Local Coverage Article: Billing and Coding: Vitamin D Assay Testing (A57719)²

Both assays of Vitamin D (25-OH vitamin D and 1,25-dihydroxy vitamin D) need not be performed for each of conditions listed in criterion I. or III, above. Documentation must justify the test(s) chosen for a particular disease entity. Various component sources of 25-OH vitamin D, such as stored D or diet-derived D, should not be billed separately.

Once a beneficiary has been shown to be vitamin D deficient, further testing may be medically necessary only to ensure adequate replacement has been accomplished. If vitamin D level is between 20 and 50 ng/ml and patient is clinically stable, repeat testing is often unnecessary; if performed, documentation must clearly indicate the necessity of the test.

Testing should be limited to no more than four per year.

CODES*		
CPT	0038U	Vitamin D, 25 hydroxy D2 and D3, by LC-MS/MS, serum microsample, quantitative
	82306	Vitamin D; 25 hydroxy, includes fraction(s), if performed
	82652	Vitamin D; 1, 25 dihydroxy, includes fraction(s), if performed

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- See the non-covered and prior authorization lists on the Company [Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website](#) for additional information.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): Vitamin D Assay Testing (L34051). <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34051>. Published 2019. Accessed 1/29/2024.
2. Centers for Medicare & Medicaid Services. Local Coverage Article: Billing and Coding: Vitamin D Assay Testing (A57719). <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=57719>. Published 2023. Accessed 1/29/2024.
3. Centers for Medicare & Medicaid Services. Local Coverage Article: Response to Comments: Vitamin D Assay Testing (A55373). <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=55373>. Published 2017. Accessed 1/29/2024.
4. U.S. Preventive Services Task Force. Vitamin D Deficiency: Screening. <https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/vitamin-d-deficiency-screening?ds=1&s=vitamin> D. Published 2021. Accessed 1/29/2024.
5. Choosing Wisely®. American Society for Clinical Pathology. Recommendations on screening for Vitamin D deficiency. Released February 21, 2013. <http://www.choosingwisely.org/clinician-lists/american-society-clinical-pathology-population-based-screening-for-vitamin-d-deficiency/>. Accessed 1/29/2024.
6. Choosing Wisely®. Endocrine Society. Recommendation on 1,25-dihydroxyvitamin D testing. Released October 16, 2013. <http://www.choosingwisely.org/clinician-lists/endocrine-society-vitamin-d-testing/>. Accessed 1/29/2024.
7. Holick MF, Binkley NC, Bischoff-Ferrari HA, et al. Evaluation, treatment, and prevention of vitamin D deficiency: an Endocrine Society clinical practice guideline. *The Journal of clinical*

endocrinology and metabolism. 2011;96(7):1911-1930. <https://academic.oup.com/jcem/article/96/7/1911/2833671>.

8. National Institutes for Health and Care Excellence. Multiple sclerosis in adults: management. <https://www.nice.org.uk/guidance/ng220>. Published 2022. Accessed 1/29/2024.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
4/2023	Annual update; no changes to criteria
4/2024	Annual update; no changes to criteria. Change in diagnosis code configuration per CMS update.