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Medicare Advantage Policy Manual

Policy ID: M-LAB52

Vitamin D Testing

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG[™] criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

"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." (Noridian LCD L34051)

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*	None
National Coverage Determinations (NCDs)*	None

Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles*

Non-Noridian Healthcare Solutions LCDs and Articles* Vitamin D Assay Testing ($\underline{L34051}$) (The companion article A57719 and prior versions of the LCD can be accessed directly from the LCD)

For the Sensieva[™] Droplet 25OH Vitamin D2/D3 Microvolume LC/MS Assay (0038U):

- ✓ The MoIDX Program requires labs to submit a technology assessment (TA) to provide evidence of analytical and clinical validity (AV/CV), and clinical utility (CU). (Noridian Article A54552)
- ✓ The Noridian LCD L35160 states reimbursement is only allowed for "approved tests… for dates of service consistent with the effective date of the coverage determination" after MoIDX review.
- If a test does not have a coverage determination, then coverage is not allowed because evidence of clinical validity or utility has not been established via the TA review process.
- ✓ This test is not considered medically reasonable and necessary under SSA §1862(a)(1)(A) until a MoIDX review is complete and coverage is indicated by MoIDX or Noridian.

Note: This test is performed by InSource Diagnostics (Monrovia, CA). Medicare guidelines state jurisdiction for coverage determinations for diagnostic laboratory services is by the contractor assigned jurisdiction over the service area in which the tests are performed.^[1,2] Therefore, the Medicare contractor for California (Noridian, Jurisdiction E, or J-E) is responsible for establishing coverage determinations.

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below <u>must</u> be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- The vitamin D assay requested (measurement of 25-OH vitamin D [CPT 82306], measurement of 1, 25-OH vitamin D [CPT 82652], or the Sensieva[™] Droplet 25OH Vitamin D2/D3 Microvolume LC/MS Assay [CPT 0038U];
- The disease or condition necessitating the required assay test;
- Any and all repeat testing and frequency of testing.

CROSS REFERENCES

None

REFERENCES

- 1. Medicare Claims Processing Manual, Chapter 1 General Billing Requirements, <u>§10.1.5.4 -</u> Independent Laboratories
- 2. Medicare Managed Care Manual, Chapter 4 Benefits and Beneficiary Protections, <u>§90.4.1</u> - MAC with Exclusive Jurisdiction over a Medicare Item or Service

CODING		
Codes	Number	Description
СРТ	0038U	25OH Vitamin D2, 25OH Vitamin D3, and total 25OH Vitamin D, by liquid chromatography with tandem mass spectrometry (LC-MS/MS), blood, quantitative, micro-volume assay
	82306	Vitamin D; 25 hydroxy, includes fraction(s), if performed
	82652	Vitamin D; 1,25 dihydroxy, includes fraction(s), if performed
HCPCS	None	

*IMPORTANT NOTE: Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.