

Local Coverage Determination (LCD): Vitamin D Assay Testing (L33996)

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
CGS Administrators, LLC	MAC - Part A	15101 - MAC A	J - 15	Kentucky
CGS Administrators, LLC	MAC - Part B	15102 - MAC B	J - 15	Kentucky
CGS Administrators, LLC	MAC - Part A	15201 - MAC A	J - 15	Ohio
CGS Administrators, LLC	MAC - Part B	15202 - MAC B	J - 15	Ohio

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LCD Information

Document Information

LCD ID L33996	Original Effective Date For services performed on or after 10/01/2015
Original ICD-9 LCD ID L31910	Revision Effective Date For services performed on or after 05/01/2017
LCD Title Vitamin D Assay Testing	Revision Ending Date N/A
Proposed LCD in Comment Period N/A	Retirement Date N/A
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CMS National Coverage Policy

Language quoted from Centers for Medicare and Medicaid Services (CMS). National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals is italicized throughout the policy. NCDs and coverage provisions in interpretive manuals are not subject to the Local Coverage Determination (LCD) Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See Section 1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, *italicized* text represents quotation from one or more of the following CMS sources:

Title XVIII of the Social Security Act (SSA):

Section 1862(a)(1)(A) excludes expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Section 1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Abstract:

Vitamin D is a hormone, synthesized by the skin and metabolized by the kidney to an active hormone, calcitriol. An excess of vitamin D may lead to hypercalcemia. Vitamin D deficiency may lead to a variety of disorders. This LCD identifies the indications and limitations of Medicare coverage and reimbursement for these services.

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 really a hormone, synthesized by the skin and metabolized by the kidney to an active hormone, calcitriol, which then acts throughout the body. In the skin, 7-dehydrocholesterol is converted to vitamin D3 in response to sunlight, a process that is inhibited by sunscreen with a skin protection factor (SPF) of 8 or greater. Once in the blood, vitamin D2 and D3 from diet or skin bind with vitamin D binding protein and are carried to the liver where they are hydroxylated to yield calcidiol. Calcidiol then is converted in the kidney to calcitriol by the action of 1 α -hydroxylase (CYP27B1). The CYP27B1 in the kidney is regulated by nearly every hormone involved in calcium homeostasis, and its activity is stimulated by PTH, estrogen, calcitonin, prolactin, growth hormone, low calcium levels, and low phosphorus levels. Its activity is inhibited by calcitriol, thus providing the feedback loop that regulates calcitriol synthesis.

An excess of vitamin D is unusual, but may lead to hypercalcemia. Vitamin D deficiency may lead to a variety of disorders, the most infamous of which is rickets. Evaluating patients' vitamin D levels is accomplished by measuring the level of 25-hydroxyvitamin D. Measurement of other metabolites is generally not medically necessary.

Indications:

Measurement of vitamin D levels is indicated for patients with:

- chronic kidney disease stage III or greater;
- osteoporosis;
- osteomalacia;
- osteopenia;
- hypocalcemia;

- hypercalcemia;
- hypercalciuria;
- hypoparathyroidism;
- hyperparathyroidism;
- malabsorption states;
- cirrhosis;
- hypervitaminosis D;
- obstructive jaundice;
- osteosclerosis/petrosis;
- rickets;
- low exposure to sunlight; and
- vitamin D deficiency to monitor the efficacy of replacement therapy.

Limitations:

For Medicare beneficiaries, screening tests are governed by statute. Vitamin D testing may not be used for routine screening.

Once a beneficiary has been shown to be vitamin D deficient, further testing is medically necessary only to ensure adequate replacement has been accomplished. Thereafter, annual testing may be appropriate depending upon the indication and other mitigating factors.

Other Comments:

For claims submitted to the Part A MAC: This coverage determination also applies within states outside the primary geographic jurisdiction with facilities that have nominated CGS Administrators to process their claims.

Bill type codes only apply to providers who bill these services to the Part A MAC. Bill type codes do not apply to physicians, other professionals and suppliers who bill these services to the carrier or Part B MAC.

For dates of service prior to April 1, 2010, FQHC services should be reported with bill type 73X. For dates of service on or after April 1, 2010, bill type 77X should be used to report FQHC services.

Limitation of liability and refund requirements apply when denials are likely, whether based on medical necessity or other coverage reasons. The provider/supplier must notify the beneficiary in writing, prior to rendering the service, if the provider/supplier is aware that the test, item or procedure may not be covered by Medicare. The limitation of liability and refund requirements do not apply when the test, item or procedure is statutorily excluded, has no Medicare benefit category or is rendered for screening purposes.

For outpatient settings other than CORFs, references to "physicians" throughout this policy include non-physicians, such as nurse practitioners, clinical nurse specialists and physician assistants. Such non-physician practitioners, with certain exceptions, may certify, order and establish the plan of care for Vitamin D Assay Testing services as authorized by State law. (See Sections 1861[s][2] and 1862[a][14] of Title XVIII of the Social Security Act; 42 CFR, Sections 410.74, 410.75, 410.76 and 419.22; 58 FR 18543, April 7, 2000.)

Summary of Evidence

N/A

**Analysis of Evidence
(Rationale for Determination)**

N/A

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Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

011x Hospital Inpatient (Including Medicare Part A)
012x Hospital Inpatient (Medicare Part B only)
013x Hospital Outpatient
014x Hospital - Laboratory Services Provided to Non-patients
018x Hospital - Swing Beds
021x Skilled Nursing - Inpatient (Including Medicare Part A)
022x Skilled Nursing - Inpatient (Medicare Part B only)
023x Skilled Nursing - Outpatient
071x Clinic - Rural Health
072x Clinic - Hospital Based or Independent Renal Dialysis Center
073x Clinic - Freestanding
077x Clinic - Federally Qualified Health Center (FQHC)
085x Critical Access Hospital

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

Revenue codes only apply to providers who bill these services to the Part A MAC. Revenue codes do not apply to physicians, other professionals and suppliers who bill these services to the carrier or Part B MAC.

Please note that not all revenue codes apply to every type of bill code. Providers are encouraged to refer to the FISS revenue code file for allowable bill types. Similarly, not all revenue codes apply to each CPT/HCPCS code. Providers are encouraged to refer to the FISS HCPCS file for allowable revenue codes.

All revenue codes billed on the inpatient claim for the dates of service in question may be subject to review.

0300 Laboratory - General Classification
0301 Laboratory - Chemistry
0309 Laboratory - Other Laboratory

CPT/HCPCS Codes

Group 1 Paragraph: N/A

Group 1 Codes:

82306 VITAMIN D; 25 HYDROXY, INCLUDES FRACTION(S), IF PERFORMED

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph:

It is the responsibility of the provider to code to the highest level specified in the ICD-10-CM. The correct use of an ICD-10-CM code listed below does not assure coverage of a service. The service must be reasonable and necessary in the specific case and must meet the criteria specified in this determination.

Group 1 Codes:

ICD-10 Codes	Description
E20.0	Idiopathic hypoparathyroidism
E20.8	Other hypoparathyroidism
E20.9	Hypoparathyroidism, unspecified
E21.0 - E21.3	Primary hyperparathyroidism - Hyperparathyroidism, unspecified
E41	Nutritional marasmus
E43	Unspecified severe protein-calorie malnutrition
E55.0	Rickets, active
E55.9	Vitamin D deficiency, unspecified
E67.3	Hypervitaminosis D
E67.8	Other specified hyperalimentation
E68	Sequelae of hyperalimentation
E83.31	Familial hypophosphatemia
E83.32	Hereditary vitamin D-dependent rickets (type 1) (type 2)
E83.39	Other disorders of phosphorus metabolism
E83.51	Hypocalcemia
E83.52	Hypercalcemia
E84.0	Cystic fibrosis with pulmonary manifestations
E84.11	Meconium ileus in cystic fibrosis
E84.19	Cystic fibrosis with other intestinal manifestations
E84.8	Cystic fibrosis with other manifestations
E89.2	Postprocedural hypoparathyroidism
K50.00	Crohn's disease of small intestine without complications
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.018	Crohn's disease of small intestine with other complication
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.113	Crohn's disease of large intestine with fistula
K50.114	Crohn's disease of large intestine with abscess
K50.118	Crohn's disease of large intestine with other complication
K50.80	Crohn's disease of both small and large intestine without complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.913	Crohn's disease, unspecified, with fistula
K50.914	Crohn's disease, unspecified, with abscess
K50.918	Crohn's disease, unspecified, with other complication
K51.00	Ulcerative (chronic) pancolitis without complications
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013	Ulcerative (chronic) pancolitis with fistula
K51.014	Ulcerative (chronic) pancolitis with abscess
K51.018	Ulcerative (chronic) pancolitis with other complication
K51.20	Ulcerative (chronic) proctitis without complications
K51.211	Ulcerative (chronic) proctitis with rectal bleeding
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction
K51.213	Ulcerative (chronic) proctitis with fistula
K51.214	Ulcerative (chronic) proctitis with abscess
K51.218	Ulcerative (chronic) proctitis with other complication
K51.30	Ulcerative (chronic) rectosigmoiditis without complications

ICD-10 Codes	Description
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication
K51.40	Inflammatory polyps of colon without complications
K51.411	Inflammatory polyps of colon with rectal bleeding
K51.412	Inflammatory polyps of colon with intestinal obstruction
K51.413	Inflammatory polyps of colon with fistula
K51.414	Inflammatory polyps of colon with abscess
K51.418	Inflammatory polyps of colon with other complication
K51.50	Left sided colitis without complications
K51.511	Left sided colitis with rectal bleeding
K51.512	Left sided colitis with intestinal obstruction
K51.513	Left sided colitis with fistula
K51.514	Left sided colitis with abscess
K51.518	Left sided colitis with other complication
K52.0	Gastroenteritis and colitis due to radiation
K70.2	Alcoholic fibrosis and sclerosis of liver
K70.30	Alcoholic cirrhosis of liver without ascites
K70.31	Alcoholic cirrhosis of liver with ascites
K74.1	Hepatic sclerosis
K74.2	Hepatic fibrosis with hepatic sclerosis
K76.9	Liver disease, unspecified
K90.0	Celiac disease
K90.1	Tropical sprue
K90.2	Blind loop syndrome, not elsewhere classified
K90.3	Pancreatic steatorrhea
K90.41	Non-celiac gluten sensitivity
K90.49	Malabsorption due to intolerance, not elsewhere classified
K90.89	Other intestinal malabsorption
K90.9	Intestinal malabsorption, unspecified
K91.2	Postsurgical malabsorption, not elsewhere classified
M80.00XA	Age-related osteoporosis with current pathological fracture, unspecified site, initial encounter for fracture
M80.011A	Age-related osteoporosis with current pathological fracture, right shoulder, initial encounter for fracture
M80.012A	Age-related osteoporosis with current pathological fracture, left shoulder, initial encounter for fracture
M80.021A	Age-related osteoporosis with current pathological fracture, right humerus, initial encounter for fracture
M80.022A	Age-related osteoporosis with current pathological fracture, left humerus, initial encounter for fracture
M80.031A	Age-related osteoporosis with current pathological fracture, right forearm, initial encounter for fracture
M80.032A	Age-related osteoporosis with current pathological fracture, left forearm, initial encounter for fracture
M80.041A	Age-related osteoporosis with current pathological fracture, right hand, initial encounter for fracture
M80.042A	Age-related osteoporosis with current pathological fracture, left hand, initial encounter for fracture
M80.051A	Age-related osteoporosis with current pathological fracture, right femur, initial encounter for fracture
M80.052A	Age-related osteoporosis with current pathological fracture, left femur, initial encounter for fracture
M80.061A	Age-related osteoporosis with current pathological fracture, right lower leg, initial encounter for fracture
M80.062A	Age-related osteoporosis with current pathological fracture, left lower leg, initial encounter for fracture
M80.071A	

ICD-10 Codes	Description
	Age-related osteoporosis with current pathological fracture, right ankle and foot, initial encounter for fracture
M80.072A	Age-related osteoporosis with current pathological fracture, left ankle and foot, initial encounter for fracture
M80.08XA	Age-related osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
M81.0	Age-related osteoporosis without current pathological fracture
M81.6	Localized osteoporosis [Lequesne]
M81.8	Other osteoporosis without current pathological fracture
M83.0 - M83.5	Puerperal osteomalacia - Other drug-induced osteomalacia in adults
M83.8	Other adult osteomalacia
M85.80	Other specified disorders of bone density and structure, unspecified site
M85.811	Other specified disorders of bone density and structure, right shoulder
M85.812	Other specified disorders of bone density and structure, left shoulder
M85.821	Other specified disorders of bone density and structure, right upper arm
M85.822	Other specified disorders of bone density and structure, left upper arm
M85.831	Other specified disorders of bone density and structure, right forearm
M85.832	Other specified disorders of bone density and structure, left forearm
M85.841	Other specified disorders of bone density and structure, right hand
M85.842	Other specified disorders of bone density and structure, left hand
M85.851	Other specified disorders of bone density and structure, right thigh
M85.852	Other specified disorders of bone density and structure, left thigh
M85.861	Other specified disorders of bone density and structure, right lower leg
M85.862	Other specified disorders of bone density and structure, left lower leg
M85.871	Other specified disorders of bone density and structure, right ankle and foot
M85.872	Other specified disorders of bone density and structure, left ankle and foot
M85.88	Other specified disorders of bone density and structure, other site
M85.89	Other specified disorders of bone density and structure, multiple sites
M89.9	Disorder of bone, unspecified
M94.9	Disorder of cartilage, unspecified
N18.3 - N18.6	Chronic kidney disease, stage 3 (moderate) - End stage renal disease
N25.81	Secondary hyperparathyroidism of renal origin
Q78.2	Osteopetrosis

ICD-10 Codes that DO NOT Support Medical Necessity N/A

ICD-10 Additional Information [Back to Top](#)

General Information

Associated Information

The patient's medical record must contain documentation that fully supports the medical necessity for services included within this LCD. (See "Indications and Limitations of Coverage.") This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

Sources of Information

This bibliography presents those sources that were obtained during the development of this policy. CGS Administrators is not responsible for the continuing viability of Web site addresses listed below.

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Bibliography

N/A

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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
05/01/2017	R7	<p>R7 Revision Effective: 05/01/2017 Revision Explanation: Adding dx: E67.8, E68, E84.0, E84.11, E84.19, E84.8, K50.00, K50.011, k50.012, k50.013, K50.014, K50.018, K50.111, K50.112, K50.113, K50.114, K50.118, K50.80, K50.811, K50.812, K50.813, K50.814, K50.818, K50.90, k50.911, K50.912, K50.913, K50.914, K50.918, K51.00, K51.011, K51.012, K51.013, K51.014, K51.018, K51.20, K51.211, K51.212, K51.213, K51.214, K51.218, K51.30, K51.311, K51.312, K51.313, K51.314, K51.318, K51.40, K51.411, K51.412, K51.413, K51.414, K51.418, K51.50, K51.511, K51.512, K51.513, K51.514, K51.518, K52.0, k70.2, K70.30, K70.31, K74.1, K74.3, K74.4, K74.69, M80.00XA, M80.011A, M80.012A, M80.021A, M80.022A, M80.031A, M80.032A, M80.041A, M80.042A, M80.051A, M80.052A, M80.061A, M80.062A, M80.071A, M80.072A, M80.08XA.</p> <p><i>07/05/2017-At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</i></p>	<ul style="list-style-type: none"> Reconsideration Request
10/01/2016	R6	<p>R6 Revision Effective: N/A Revision Explanation: Annual review no changes made.</p>	<ul style="list-style-type: none"> Other (Annual Review)
10/01/2016	R5	<p>R5 Revision Effective: 10/01/2016 Revision Explanation: Added new ICD-10 codes K90.41 and K90.49 that replaced K90.4.</p>	<ul style="list-style-type: none"> Revisions Due To ICD -10-CM Code Changes
05/01/2016	R4	<p>R4 Revision Effective: 05/01/2016 Revision Explanation: Added the following indications and ICD-10 codes to correlate to additional indications for vitamin D testing: hypercalciura, malabsorption states, cirrhosis, hypervitaminosis D, obstructive jaundice, osteosclerosis/petrosis, and low exposure to sunlight.</p>	<ul style="list-style-type: none"> Reconsideration Request
10/01/2015	R3	<p>R3 Revision Effective: 10/01/2015 Revision Explanation: Added M85.80 as showing medical necessity.</p>	<ul style="list-style-type: none"> Reconsideration Request
10/01/2015	R2	<p>R2 Revision Effective: 10/01/2015 Revision Explanation: Added ICD-10 codes in the M85.8 series.</p>	<ul style="list-style-type: none"> Reconsideration Request
10/01/2015	R1	<p>R1 Revision Effective: N/A Revision Explanation: Annual review no changes made.</p>	<ul style="list-style-type: none"> Other (Annual Review)

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Related National Coverage Documents N/A

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