

# LCD - Assays for Vitamins and Metabolic Function (L34914)

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## Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	04111 - MAC A	J - H	Colorado
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	04112 - MAC B	J - H	Colorado
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	04211 - MAC A	J - H	New Mexico
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	04212 - MAC B	J - H	New Mexico
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	04311 - MAC A	J - H	Oklahoma
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	04312 - MAC B	J - H	Oklahoma
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	04411 - MAC A	J - H	Texas
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	04412 - MAC B	J - H	Texas
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	04911 - MAC A	J - H	Colorado New Mexico Oklahoma Texas
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	07101 - MAC A	J - H	Arkansas
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	07102 - MAC B	J - H	Arkansas
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	07201 - MAC A	J - H	Louisiana
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	07202 - MAC B	J - H	Louisiana
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	07301 - MAC A	J - H	Mississippi
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	07302 - MAC B	J - H	Mississippi
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	12101 - MAC A	J - L	Delaware
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	12102 - MAC B	J - L	Delaware
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	12201 - MAC A	J - L	District of Columbia
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	12202 - MAC B	J - L	District of Columbia
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	12301 - MAC A	J - L	Maryland
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	12302 - MAC B	J - L	Maryland
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	12401 - MAC A	J - L	New Jersey
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	12402 - MAC B	J - L	New Jersey
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	12501 - MAC A	J - L	Pennsylvania
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	12502 - MAC B	J - L	Pennsylvania
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	12901 - MAC A	J - L	Delaware

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
				District of Columbia Maryland New Jersey Pennsylvania

# LCD Information

## Document Information

### LCD ID

L34914

### LCD Title

Assays for Vitamins and Metabolic Function

### Proposed LCD in Comment Period

N/A

### Source Proposed LCD

[DL34914](#)

### Original Effective Date

For services performed on or after 10/01/2015

### Revision Effective Date

For services performed on or after 07/01/2020

### Revision Ending Date

N/A

### Retirement Date

N/A

### Notice Period Start Date

06/16/2016

### Notice Period End Date

08/03/2016

## CMS National Coverage Policy

This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for vitamins and metabolic function assay services. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or

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supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for vitamins and metabolic function assay services and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies may be found in the following Internet-Only Manuals (IOMs) published on the CMS Web site:

#### **IOM Citations:**

- CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*,
  - Chapter 6, Section 20.4 Outpatient Diagnostic Services
  - Chapter 15, Section 80.1 Clinical Laboratory Services
- CMS IOM Publication 100-03, *Medicare National Coverage Determinations (NCD) Manual*,
  - Chapter 1, Part 4, Section 230.19 Levocarnitine for use in the Treatment of Carnitine Deficiency in ESRD Patients
- CMS IOM Publication 100-04, *Medicare Claims Processing Manual*,
  - Chapter 16, Laboratory Services
  - Chapter 23, Section 10 Reporting ICD Diagnosis and Procedure codes and Section 40 Clinical Diagnostic Laboratory Fee Schedule
- CMS IOM Publication 100-08, *Medicare Program Integrity Manual*,
  - Chapter 13, Section 13.5.4 Reasonable and Necessary Provision in an LCD

#### **Social Security Act (Title XVIII) Standard References:**

- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.

## **Coverage Guidance**

### **Coverage Indications, Limitations, and/or Medical Necessity**

Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.

### **Covered Indications**

Medicare generally considers vitamin assay panels (more than one vitamin assay) a screening procedure and therefore, non-covered. Similarly, assays for micronutrient testing for nutritional deficiencies that include multiple tests for vitamins, minerals, antioxidants and various metabolic functions are never necessary. Medicare reimburses for covered clinical laboratory studies that are reasonable and necessary for the diagnosis or treatment of an illness. Many vitamin deficiency problems can be determined from a comprehensive history and physical examination. Any diagnostic evaluation should be targeted at the specific vitamin deficiency suspected and not a general screen. Most vitamin deficiencies are nutritional in origin and may be corrected with supplemented vitamins.

Most vitamin deficiencies are suggested by specific clinical findings. The presence of those specific clinical findings may prompt laboratory testing for evidence of a deficiency of that specific vitamin. Certain other clinical states may also lead to vitamin deficiencies (malabsorption syndromes, etc.).

**Limitations:**

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

Once a beneficiary has been shown to be vitamin 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.

**Notice:** This LCD imposes the following limitations to the tests addressed in this LCD. Refer to the companion article Billing and Coding: Assays for Vitamins and Metabolic Function, A56416, for all coding information. These limitations will support automated denials as follows:

- Diagnosis to procedure limitations only for cellular function assays involving stimulation and detection of biomarker
- Frequency limitations\*\* only for:
  - Assay of ascorbic acid
  - Assay of vitamin b-2
  - Assay of vitamin b-1
  - Assay of vitamin e
  - Assay of vitamin a
  - Assay of vitamin k
- Diagnosis to procedure and frequency limitations\*\* for:
  - Vitamin d 25 hydroxy
  - Assay of carnitine
  - Vitamin b-12
  - Vitamin d 1 25-dihydroxy
  - Assay of folic acid serum
  - Assay of homocysteine
  - Assay lipoprotein pla2
  - Assay of vitamin b-6
  - Fibrinogen antigen

**\*\*Note:** This LCD imposes frequency limitations. Please refer to the Utilization Guidelines section for an outline of the frequency limitations. Frequency limitations do not establish medical necessity for all testing but does reflect how the medical community uses the tests. Patterns of billing will be monitored for potential utilization of these tests for screening purposes, either by use of a single test or multiple tests together.

**Notice:** Services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

The redetermination process may be utilized for consideration of services performed outside of the reasonable and necessary requirements in this LCD.

**Summary of Evidence**

N/A

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

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# General Information

## Associated Information

Refer to the Local Coverage Article: Billing and Coding: Assays for Vitamins and Metabolic Function, A56416, for all coding information.

## Documentation Requirements

1. All documentation must be maintained in the patient's medical record and made available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service[s]). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
3. The medical record documentation must support the medical necessity of the services as stated in this policy.

## Utilization Guidelines

In accordance with CMS Ruling 95-1 (V), utilization of these services should be consistent with locally acceptable standards of practice.

Medicare recognizes certain tests may exceed the stated frequencies. Should a denial occur, additional documentation can be submitted to support medical necessity. Payment for additional tests may be allowed in selected circumstances when, upon medical review, the medical necessity of additional services is demonstrated.

Following a review of utilization data at various percentiles of units billed per year, the following frequency limitations are established and are as follows:

Assay of ascorbic acid, 1 time per year  
Vitamin d 25 hydroxyl, up to 3 times per year  
Assay of carnitine, up to 3 times per year  
Vitamin b-12, up to 3 times per year  
Vitamin d 1 25-dihydroxy, up to 2 times per year  
Assay of folic acid serum, up to 3 times per year  
Assay of homocysteine, 1 time per year  
Assay lipoprotein pla2, 1 time per year  
Assay of vitamin b-6, 1 time per year  
Assay of vitamin b-2, 1 time per year  
Assay of vitamin b-1, 1 time per year  
Assay of vitamin e, 1 time per year  
Assay of vitamin a, 1 time per year  
Assay of vitamin k, 1 time per year  
Fibrinogen antigen, up to 3 times per year  
Cell function assay w/stim frequencies not determined

**Notice:** This LCD imposes utilization guideline limitations. Despite Medicare's allowing up to these maximums, each patient's condition and response to treatment must medically warrant the number of services reported for payment. Medicare requires the medical necessity for each service reported to be clearly demonstrated in the patient's medical record. Medicare expects that patients will not routinely require the maximum allowable number of services.

## Sources of Information

Contractor is not responsible for the continued viability of websites listed.

Novitas Solutions, Inc. Local Coverage Determination (LCD): Vitamin D Assay Testing (L34888)

Other Contractor Policies

Palmetto GBA Local Coverage Determination (LCD): Assays for Vitamins and Metabolic Function (L33418)

Palmetto GBA Local Coverage Determination (LCD): MoIDX: Biomarkers in Cardiovascular Risk Assessment (L36129)

Noridian Healthcare Solutions, LLC Local Coverage Determination (LCD): Non Covered Services (L36219)

National Government Services, LCD on Vitamin D assay testing (L29510).

Noridian Local Medical Review Policy, "Folic Acid, Serum."

Contractor Medical Directors

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## Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
07/01/2020	R14	LCD revised and published on June 25, 2020 effective for dates of service on and after 07/01/2020, as a non-discretionary update to remove the list of non-covered services in the limitations section. Minor formatting changes have been made.	<ul style="list-style-type: none"><li>Other (Revised in response to CMS direction)</li></ul>
10/17/2019	R13	LCD revised and published on 10/17/2019. Consistent with CMS Change Request 10901, the entire coding section has been removed from the LCD and placed into the related Billing and Coding Article, A56416. All CPT codes and coding information within the text of the LCD has been placed in the Billing and Coding Article.	<ul style="list-style-type: none"><li>Other (CMS Change Request 10901)</li></ul>
03/28/2019	R12	LCD revised and published on 03/28/2019. The IOM Citations section was revised to add applicable manual references and to remove the reference to NCCI since coding and billing information has been moved to the companion article. All billing and coding related information has been moved to companion article Billing and Coding: Assays for Vitamins and Metabolic Function, A56416, consistent with CMS Change Request (CR) 10901. References listed in the Sources section of the LCD have been moved to the Bibliography section.	<ul style="list-style-type: none"><li>Other (Change in LCD process per CMS CR 10901)</li></ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		Links have been added to the companion article, A56416, and NCD 230.19.	
10/01/2018	R11	<p>LCD revised and published on 10/25/2018 effective for dates of service on and after 10/01/2018 to reflect the Annual ICD-10-CM Code Updates. The following ICD-10-CM codes have been deleted and therefore removed from the LCD: E78.4 and M79.1. The following ICD-10-CM codes have been added to the LCD Group 1 codes: M79.11, M79.12, and M79.18. The following ICD-10-CM code has been added to the LCD Group 7 codes: E78.49. The following ICD-10-CM code has undergone a descriptor change: Z68.43.</p> <p>Per LCD annual review, updated the SSA references in the "CMS National Coverage Policy" section and expanded the following ranges in Group 1 for diagnosis codes that were previously listed in a ranged format (without a change in coverage content): B38.1 – B38.9, B39.1 – B39.9, C82.00 – C82.99, and Z68.30 – Z68.45.</p> <p>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; therefore, not all the fields included on the LCD are applicable as noted in this policy.</p>	<ul style="list-style-type: none"> <li>• Revisions Due To ICD-10-CM Code Changes</li> <li>• Other (Annual Review)</li> </ul>
10/01/2017	R10	<p>LCD revised and published on 10/05/2017 effective for dates of service on and after 10/01/2017 to reflect the Annual ICD-10-CM Code Updates. The following ICD-10-CM codes have undergone a descriptor change: Group 1 codes M33.00, M33.01, M33.02, M33.09, M33.10, M33.11, M33.12, and M33.19.</p> <p>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; therefore, not all the fields included on the LCD are applicable as noted in this policy.</p>	<ul style="list-style-type: none"> <li>• Revisions Due To ICD-10-CM Code Changes</li> </ul>
02/03/2017	R9	<p>LCD revised and published on 04/13/2017 effective for dates of service on and after 02/03/2017 to add ICD-10 code M85.80 as a covered diagnosis to the Group 1 codes.</p> <p>Reformatted the CPT code groups to align with their respective ICD-10 code groups. Added short descriptors to the CPT Codes in the Utilization Guidelines.</p>	<ul style="list-style-type: none"> <li>• Other (Inquiry Clarification)</li> </ul>



REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
10/01/2016	R8	LCD revised and published on 10/13/2016 effective for dates of service on and after 10/01/2016 to reflect the ICD-10 Annual Code Updates. The following ICD-10 code has been added to the LCD Group 1 codes: K90.49.	<ul style="list-style-type: none"> <li>Revisions Due To ICD-10-CM Code Changes</li> </ul>
10/01/2016	R7	LCD revised and published on 09/29/2016 effective for dates of service on and after 10/01/2016 to reflect the ICD-10 Annual Code Updates. The following ICD-10 code(s) have been deleted and therefore removed from the LCD: Group 1 code K90.4, Group 3 code K90.4 and Group 7 code E78.0. The following ICD-10 code(s) have been added to the LCD: Group 3 code K90.49 and Group 7 codes E78.00 and E78.01.	<ul style="list-style-type: none"> <li>Revisions Due To ICD-10-CM Code Changes</li> </ul>
08/04/2016	R6	The following ICD-10-CM diagnoses codes were added to the Group 7 codes as covered diagnoses: E11.65, E11.9, E13.9, E78.0, E78.1, E78.2, E78.3, and E78.4.	<ul style="list-style-type: none"> <li>Other (Clarification)</li> </ul>
08/04/2016	R5	LCD posted for notice on 06/16/2016. LCD becomes effective for dates of service on and after 08/04/2016.  01/22/2016 DL34914 Draft LCD posted for comment.	<ul style="list-style-type: none"> <li>Aberrant Local Utilization</li> </ul>
04/07/2016	R4	LCD revised and published on 04/14/2016 effective for dates of service on and after 04/07/2016 to remove CPT code 86141 (hsCRP) from this LCD. Refer to LCD L34856 for coverage of CPT code 86141.	<ul style="list-style-type: none"> <li>Other (Clarification)</li> </ul>
10/01/2015	R3	LCD revised and published on 02/11/2016 effective for dates of service on and after 10/01/2015 to add several ICD-10 codes as covered diagnoses. E55.0 added to Group 1, E44.0; F03.90; G30.0; G30.1; G30.8; G30.9; K14.0; K31.8; K50.012-K50.014; K50.112-K50.114; K50.812-K50.814; K50.912-K50.914; R20.0-R20.9 and R41.82 added to Group 3, D64.0-D64.3 and K14.0 added to Group 4, D69.49 added to Group 5, Z94.3 added to Group 6, E11.65; E11.9; E13.9; E78.0-E78.5; I25.110-I25.119 and I25.84 added to Group 7, and E78.0 added to Group 8.	<ul style="list-style-type: none"> <li>Other (Inquiry, Clarification )</li> </ul>
10/01/2015	R2	LCD revised and published 10/29/2015 effective for dates of service 10/01/2015 and after to add additional ICD-10 codes with higher specificity.	<ul style="list-style-type: none"> <li>Other (Clarification)</li> </ul>
10/01/2015	R1	LCD revised and published on 10/08/2015 to remove CPT code 86353 from the Diagnosis Code Group 6. Notation for NCD 190.8 added.	<ul style="list-style-type: none"> <li>NCD Supplementation</li> </ul>

# Associated Documents

## Attachments

N/A

## Related Local Coverage Documents

## Articles

[A56416 - Billing and Coding: Assays for Vitamins and Metabolic Function](#)

## Related National Coverage Documents

N/A

## Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
06/19/2020	07/01/2020 - N/A	Currently in Effect (This Version)
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.		

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# Keywords

N/A