Local Coverage Determination (LCD) for Lipid Profile/Cholesterol Testing (L27352)

Contractor Information
Contractor Name
National Government Services, Inc. opens in new window
Contractor Number
13282
Contractor Type
MAC - Part B

LCD Information
Document Information
LCD ID Number
L27352

LCD Title
Lipid Profile/Cholesterol Testing

Contractor's Determination Number
L27352 (R8)

Primary Geographic Jurisdiction opens in new window
New York - Upstate

Oversight Region
Region I

Original Determination Effective Date
For services performed on or after 11/15/2008

Original Determination Ending Date

Revision Effective Date
For services performed on or after 09/01/2012

Revision Ending Date

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

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 1862 (a)(7) this section excludes routine physical examinations.
Indications and Limitations of Coverage and/or Medical Necessity

Abstract

Lipoproteins are a class of heterogeneous particles of varying sizes and densities containing lipid and protein. These lipoproteins include cholesterol esters and free cholesterol, triglycerides, phospholipids and A, C, and E apoproteins. Total cholesterol comprises all the cholesterol found in various lipoproteins.

Factors that affect blood cholesterol levels include age, sex, body weight, diet, alcohol and tobacco use, exercise, genetic factors, family history, medications, menopausal status, the use of hormone replacement therapy, and chronic disorders such as hypothyroidism, obstructive liver disease, pancreatic disease diabetes and kidney disease.

In many individuals, an elevated lipid level increases the risk of developing coronary artery and other atherosclerotic disease. Blood levels of total cholesterol and various fractions of cholesterol, especially low density lipoprotein cholesterol (LDL-C) and high density lipoprotein cholesterol (HDL-C), and triglycerides are useful in assessing and monitoring treatment for that risk in patients with cardiovascular and related diseases. Therapy to reduce these risk parameters includes diet, exercise and medication.

The serum LDL concentration may be calculated using the Friedenwald formula (LDL=total cholesterol-HDL-triglycerides/5). This formula is valid only for triglyceride levels less than 400mg/dL. The LDL should be measured directly when the triglyceride level exceeds this value. This calculation may not accurately calculate the LDL in alcoholic patients. These patients may also require direct measurement of the serum LDL. This LCD defines national coverage criteria for lipid profile tests, as well as local coverage criteria for specific tests.

Indications

Conditions in which lipid testing may be indicated include:
- assessment of patients with atherosclerotic cardiovascular disease;
- evaluation of primary dyslipidemia;
- any form of atherosclerotic disease, or any disease leading to the formation of atherosclerotic disease;
- diagnostic evaluation of diseases associated with altered lipid metabolism, such as: nephrotic syndrome, pancreatitis, hepatic disease, and hypo and hyperthyroidism;
- secondary dyslipidemia, including diabetes mellitus, disorders of gastrointestinal absorption, chronic renal failure;
- signs of dyslipidemias, such as skin lesions;
• as follow up to the initial screen for coronary heart disease (total cholesterol + HDL cholesterol) when total cholesterol is determined to be high (> 240 mg/dL), or borderline-high (200-240 mg/dL) plus two or more coronary heart disease risk factors, or an HDL cholesterol <35 mg/dL.

Lipid panel and hepatic panel testing may be used for patients with severe psoriasis which has not responded to conventional therapy and for which the retinoid etretinate has been prescribed and who have developed hyperlipidemia or hepatic toxicity. Specific examples include erythrodermia and generalized pustular type of psoriasis associated with arthritis.

To monitor the progress of patients on anti lipid dietary management and pharmacologic therapy for the treatment of elevated blood lipid disorders, total cholesterol, HDL cholesterol and LDL cholesterol may be used. Triglycerides may be obtained if this lipid fraction is also elevated or if the patient is put on drugs (for example, thiazide diuretics, beta-blockers, estrogens, glucocorticoids, and tamoxifen) which may raise the triglyceride level.

Electrophoretic or other quantitation of lipoproteins may be indicated if the patient has a primary disorder of lipid metabolism (ICD-9-CM codes 272.0 to 272.9).

Limitations

Tests not ordered by a treating physician will be denied as not medically necessary.

Claims for VLDL (83719) and lipoprotein (a) (82172) will be denied as not medically necessary, since NCEP recommendations do not include monitoring of VLDL or apolipoprotein levels for treatment of elevated cholesterol as risk factors for coronary and vascular atherosclerosis.

Once a diagnosis is established, one or several specific tests are usually adequate for monitoring the course of the disease. Less specific diagnoses (for example, other chest pain) alone do not support medical necessity of these tests.

If no dietary or pharmacological therapy is advised, monitoring is not necessary and will be denied.

When evaluating non specific chronic abnormalities of the liver (for example, elevations of transaminase, alkaline phosphatase, abnormal imaging studies, etc.), a lipid panel would generally not be indicated more than twice per year.

When monitoring serum LDL levels, it is usually not necessary to obtain a lipid panel 80061 (total cholesterol, HDL and triglycerides) and a measured LDL-cholesterol (83721) on the same day, unless the serum triglyceride level is greater than 400mg/dl. Consequently, if requested on the same day as a lipid panel, the measured LDL should only be ordered as a reflex test, to be performed if the triglycerides exceed this value.

Other Comments:

For claims submitted to the fiscal intermediary or Part A MAC: this coverage determination also applies within states outside the primary geographic jurisdiction with facilities that have nominated National Government Services to process their claims.

Bill type codes only apply to providers who bill these services to the fiscal intermediary or 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.

Limitation of liability and refund requirements apply when denials are anticipated, 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 considered medically necessary 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.
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.

012x Hospital Inpatient (Medicare Part B only)
013x Hospital Outpatient
014x Hospital - Laboratory Services Provided to Non-patients
018x Hospital - Swing Beds
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 fiscal intermediary or 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 HCPS file for allowable revenue codes.

0300 Laboratory - General Classification
0301 Laboratory - Chemistry
0309 Laboratory - Other Laboratory
0971 Professional Fees - Laboratory

CPT/HCPCS Codes
CPT code 80061 Lipid panel must include procedures 82465, 83718, 84478.
80061 LIPID PANEL
82172 APOLIPOPROTEIN, EACH
82465 CHOLESTEROL, SERUM OR WHOLE BLOOD, TOTAL
83700 LIPOPROTEIN, BLOOD; ELECTROPHORETIC SEPARATION AND QUANTITATION
83701 INCLUDING LIPOPROTEIN SUBCLASSES WHEN PERFORMED (EG, ELECTROPHORESIS, ULTRACENTRIFUGATION)
83704 LIPOPROTEIN, BLOOD; QUANTITATION OF LIPOPROTEIN PARTICLE NUMBERS AND LIPOPROTEIN PARTICLE SUBCLASSES (EG, BY NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY)
83718 LIPOPROTEIN, DIRECT MEASUREMENT; HIGH DENSITY CHOLESTEROL (HDL CHOLESTEROL)
83719 LIPOPROTEIN, DIRECT MEASUREMENT; VLDL CHOLESTEROL
83721 LIPOPROTEIN, DIRECT MEASUREMENT; LDL CHOLESTEROL
84478 TRIGLYCERIDES

ICD-9 Codes that Support Medical Necessity
It is the responsibility of the provider to code to the highest level specified in the ICD-9-CM (e.g., to the fourth or fifth digit). The correct use of an ICD-9-CM code 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.

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(The listed ICD-9-CM codes are not applicable for CPT/HCPCS Codes 82172 and 83719.)

ICD-9-CM codes V81.0, V81.1 and V81.2 are only payable for CPT codes 80061, 82465, 83718 and 84478.

For the list of ICD-9 Codes that Support Medical Necessity, please refer to the covered code lists in the NCD for Lipid Testing.

XX000  Not Applicable

Diagnoses that Support Medical Necessity
Not applicable
ICD-9 Codes that DO NOT Support Medical Necessity
Not applicable

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity
Not applicable

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**General Information**

**Documentations Requirements**

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.

Each claim must be submitted with ICD-9-CM codes that reflect the condition of the patient, and indicate the reason(s) for which the service was performed. Claims submitted without ICD-9-CM codes will be returned.

The ordering physician must document in the patient's medical record conformity to this policy and/or support of the medical necessity.

Documentation of triglycerides > 400 mg/dL on the same sample must be available in the medical record when submitting a claim for direct LDL measurement (83721), when the entire lipid panel 80061 is billed for the same date.

Documentation that the patient has a history of alcoholism must be available in the medical record, if such diagnosis is the basis for direct measurement of the LDL.

Documentation of medical necessity for special lipoprotein analyses (83715 and 83716) must be maintained in the patient's medical record. The record should reflect the specific need for these tests in the diagnosis and treatment of the patient.

The patient's medical record should document ongoing treatment and/or monitoring of treatment for lipid abnormalities.

Documentation must be available to Medicare upon request. If adequate documentation cannot be obtained from the provider or ordering physician, then the claim will be denied as not medically necessary.

Appendices Not applicable

**Utilization Guidelines**

• The first follow up LDL determination and assessment of possible adverse biochemical changes should be made 6-8 weeks after initiating drug therapy. If the target LDL cholesterol is not achieved with the initial dose, then drug titration should be used to find the optimum dose - with measurements made every 6-8 weeks while medication is being adjusted.

• When monitoring long term anti-lipid therapy and following patients with borderline high total or LDL cholesterol, a lipid panel would reasonably be performed once per year.

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• After 1 year of therapy during which the response has been established and there is no evidence of biochemical
toxicity, patients should be followed at 4- to 6-month intervals - with total cholesterol or LDL.

• A yearly lipid panel would be reasonable and necessary to monitor patients with borderline high cholesterol,
who are not being treated, or in patients who are stable on dietary therapy.

• Measurement of the total serum cholesterol (CPT code 82465) or a measured LDL (CPT code 83721) should
suffice for interim visits if the patient does not have hypertriglyceridemia.

• Any one component of the panel or a measured LDL may be reasonable and necessary up to six times in the
first year for monitoring dietary or pharmacologic therapy.

More frequent total cholesterol HDL, cholesterol, LDL cholesterol and triglyceride testing may be indicated for
marked elevations or for changes to anti-lipid therapy due to inadequate initial patient response to dietary or
pharmacologic therapy.

• After treatment goals have been achieved, LDL or total cholesterol may be measured three times per year.

Sources of Information and Basis for Decision
This bibliography presents those sources that were obtained during the development of this policy. National
Government Services is not responsible for the continuing viability of Web site addresses listed below.


Cole T. The role of immunochemistry in the direct measurement of low density lipoprotein cholesterol. Journal of

Corsetti J, Sparks C. Calculated and direct LDL-cholesterol, strong health. Clinical Laboratories Newsletter (Strong

Executive summary of the national cholesterol education program expert panel-second report on detection,


Jialal I. Evolving lipoprotein risk factors: lipoprotein (a) and oxidizing low-density lipoprotein. Clin Chem.
1998;44:8(B):1827-1832.

Matas C. Limitations of the Friedewald formula for estimating low-density lipoprotein cholesterol in alcoholics with

-207.

McNamara JR, Cohn JS, Wilson PW, Schaefer EJ. Calculated values for low-density lipoprotein cholesterol in the

National Institutes of Health. Second report of the expert panel on detection, evaluation, and treatment of high

Third report of the national cholesterol education program (NCEP) expert panel on detection, evaluation, and
 treatment of high blood cholesterol in adults (Adult Treatment Panel III) final report national cholesterol
education program, national heart, lung, and blood institute, national institutes of health. NIH Publication.
2002;02-5215.

U.S. department of health and human services. National cholesterol education program, recommendations for
improving cholesterol measurement. NIH Publication. 1990;90-2964.

Advisory Committee Meeting Notes Carrier Advisory Committee Meeting Date(s):
Indiana: 05/19/2008
Kentucky: 05/22/2008
New York: 04/30/2008

This coverage determination does not reflect the sole opinion of the contractor or contractor Medical Director. Although the final decision rests with the contractor, this determination is developed in consultation with representatives from Advisory Committee members and/or from various state and local provider organizations.

Start Date of Comment Period 04/17/2008
End Date of Comment Period 05/31/2008
Start Date of Notice Period 10/01/2010

Revision History Number R8

Revision History Explanation R8 (effective 09/01/2012): Annual LCD review per CMS Program Integrity Manual, Chapter 13, Section 13.4[C]. Content reviewed, and no changes required other than for minor formatting. No comment and notice periods required and none given.

08/20/2012 - In accordance with Section 911 of the Medicare Modernization Act of 2003, carrier number 00630 is removed from this LCD. Effective on this date, claims processing for Indiana Part B is performed by Wisconsin Physician Services, the Part A/Part B MAC contractor for this state.

07/23/2012 - In accordance with Section 911 of the Medicare Modernization Act of 2003, fiscal intermediary numbers 00130 and 00452 are removed from this LCD. Effective on this date, claims processing for Indiana and Michigan is performed by Wisconsin Physician Services, the Part A/Part B MAC contractor for these states.

10/17/2011 - In accordance with Section 911 of the Medicare Modernization Act of 2003, fiscal intermediary numbers 00160 and 00332 are removed from this LCD. Effective on this date, claims processing for Kentucky –Part A and Ohio –Part A is performed by CGS Administrators, LLC, the Part A/Part B MAC contractor for these states.

R7 (effective 09/01/2011): LCD revised to replace the list of ICD-9 Codes that Support Medical Necessity with a link to the NCD for Lipid Testing, where ICD-9 Codes are maintained. No comment or notice periods required and none given.

05/16/2011 - In accordance with Section 911 of the Medicare Modernization Act of 2003, fiscal intermediary number 00453 is removed from this LCD. Effective on this date, claims processing for Virginia and West Virginia is performed by Palmetto Government Benefits Administration, the Part A/Part B MAC contractor for these states.

04/30/2011 - In accordance with Section 911 of the Medicare Modernization Act of 2003, carrier number 00660 is removed from this LCD. Effective on this date, claims processing for Kentucky is performed by Cigna Government Services, the Part A/Part B MAC contractor for this state.

Correction published 10/21/2010 (effective 10/01/2010): ICD-9-CM code 278.3 was incorrectly listed in the "Revision History Explanation" section of the LCD for the 2011 annual ICD-9-CM code update. The ICD-9-CM code that was added to the “ICD-9-CM Codes That Support Medical Necessity” section of the LCD is 278.03.

R6 (effective 10/01/2010): LCD revised for annual ICD-9-CM code updates for 2011 and CMS Transmittal #2001, Changes to the laboratory national coverage determination (NCD) edit software for October 2010. The “ICD-9-CM Codes That Support Medical Necessity” section of the policy is expanded to add ICD-9-CM code 278.3 effective for dates of service on or after 10/01/2010. No comment or notice periods required and none given.

R5 (effective 04/01/2010): Bill type instructions for reporting FQHC services updated to add bill type 77X. Abstract expanded. Minor template changes made. No comment or notice periods required and none given.

R4 (effective 10/01/2009): Annual update ICD-9-CM codes per CMS Change Request #6520, 07/10/2009 and CMS Change Request #6548, Changes to the laboratory national coverage determination (NCD) edit software for October 2009. ICD-9-CM codes 584.5 and 793.4 descriptions revised. ICD-9-CM codes 438.13 and 438.14 added to the list of ICD-9 Codes that support medical necessity. CMS publication section updated. Minor changes made to reflect current template language. No additional comment or notice periods required and none given.

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R3 (effective 07/01/2009): External (as Per CMS Transmittal 1735, Publication 100-04, Medicare Processing Manual, Change Request 6481, Changes to the Laboratory National Coverage Determination (NCD) Edit Software for July 2009) The following ICD-9-CM code will be added to the list of ICD-9-CM Codes that Support Medical Necessity, 440.4. No comment and notice periods required and none given.

06/05/2009 - In accordance with Section 911 of the Medicare Modernization Act of 2003, fiscal intermediary number 00270 was removed from this LCD as the claims processing for New Hampshire and Vermont was transitioned to NHIC, the Part A/Part B MAC contractor in these states.

05/15/2009 - In accordance with Section 911 of the Medicare Modernization Act of 2003, fiscal intermediary numbers 00180 and 00181 were removed from this LCD as the claims processing for Maine and Massachusetts was transitioned to NHIC, the Part A/Part B MAC contractor in these states.

R2 (effective 04/01/2009): External (as Per CMS Transmittal 1684, Publication 100-04, Medicare Processing Manual, Change Request 6383, February 13, 2009, Changes to the Laboratory National Coverage Determination (NCD) Edit Software for April 2009) The following ICD-9-CM code will be added to the list of ICD-9-CM Codes that Support Medical Necessity, 414.3. Minor changes were made to reflect current template language. The changes listed in this revision do NOT apply to the states of Maine (contract 00180), Massachusetts (contract 00181), or Vermont and New Hampshire (contract 00270); however, all other instructions, coverage provisions, and requirements in the LCD remain in effect for these states. No comment and notice periods required and none given.

R1 (effective 01/01/2009) External (as Per CMS Transmittal 1645, Publication 100-04, Medicare Processing Manual, Change Request 6304, December 9, 2008, Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2009) The following ICD-9-CM codes will be added to the list of ICD-9 Codes that Support Medical Necessity, 249.00-249.01, 249.10-249.11, 249.20-249.21, 249.30-249.31, 249.40-249.41, 249.50-249.51, 249.60-249.61, 249.70-249.71, 249.80-249.81, and 249.90-249.91. No comment and notice periods required and none given.

Corrected version (published 10/20/2008 during the Notice Period) (effective 11/15/2008): A typographical error in the year for the New York CAC (it should be 04/30/2008 not 04/30/2007) in the LCD has been corrected. Bill types 12X and 14X have been added to the "Bill Type Codes" section. Note added to section "ICD-9-CM Codes that Support Medical Necessity" to help providers understand the three ICD-9-CM codes that are only payable for the CPT codes in the NCD. *ICD-9-CM codes V81.0, V81.1 and V81.2 are only for CPT codes 80061, 82465, 83718 and 84478. No additional comment or notice periods required and none given.

07/18/2008 - In accordance with Section 911 of the Medicare Modernization Act of 2003, Carrier Contractor Number 00803 was removed from this LCD as the claims processing for downstate New York was transitioned to MAC Part B Contractor Number 13202.

The following are administrative notes entered by Medicare Coverage Database Contractor:

08/08/2009 - This policy was updated by the ICD-9 2009-2010 Annual Update.

3/7/2010 - The description for Bill Type Code 73 was changed

8/1/2010 - The description for Bill Type Code 12 was changed
8/1/2010 - The description for Bill Type Code 13 was changed
8/1/2010 - The description for Bill Type Code 14 was changed
8/1/2010 - The description for Bill Type Code 18 was changed
8/1/2010 - The description for Bill Type Code 22 was changed
8/1/2010 - The description for Bill Type Code 23 was changed
8/1/2010 - The description for Bill Type Code 71 was changed
8/1/2010 - The description for Bill Type Code 72 was changed
8/1/2010 - The description for Bill Type Code 73 was changed
8/1/2010 - The description for Bill Type Code 85 was changed

8/1/2010 - The description for Revenue code 0300 was changed
8/1/2010 - The description for Revenue code 0301 was changed
8/1/2010 - The description for Revenue code 0309 was changed
8/1/2010 - The description for Revenue code 0971 was changed

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11/21/2010 - For the following CPT/HCPCS codes either the short description and/or the long description was changed. Depending on which description is used in this LCD, there may not be any change in how the code displays in the document:
82465 descriptor was changed in Group 1
83700 descriptor was changed in Group 1
83701 descriptor was changed in Group 1
83704 descriptor was changed in Group 1

Reason for Change
Maintenance (annual review with new changes, formatting, etc.)

Related Documents
Article(s)
A47388 - Lipid Profile/Cholesterol Testing – Supplemental Instructions Article opens in new window

LCD Attachments
There are no attachments for this LCD.

All Versions
Updated on 08/24/2012 with effective dates 09/01/2012 - N/A
Updated on 07/31/2012 with effective dates 08/20/2012 - 08/31/2012
Updated on 07/12/2012 with effective dates 07/23/2012 - 08/19/2012
Updated on 08/25/2011 with effective dates 09/01/2011 - 10/16/2011
Updated on 05/05/2011 with effective dates 05/16/2011 - 08/31/2011
Updated on 04/11/2011 with effective dates 04/30/2011 - 05/15/2011
Updated on 11/21/2010 with effective dates 10/01/2010 - 04/29/2011
Updated on 10/13/2010 with effective dates 10/01/2010 - N/A
Updated on 09/22/2010 with effective dates 10/01/2010 - N/A
Some older versions have been archived. Please visit the MCD Archive Site opens in new window to retrieve them.

Read the LCD Disclaimer opens in new window