

Local Coverage Determination (LCD) for High Sensitivity C-Reactive Protein (hsCRP) Testing (L31839)

Contractor Information

Contractor Name CIGNA Government Services Back to Top	Contractor Number 15102	Contractor Type MAC - Part B
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LCD Information

Document Information

LCD ID Number L31839	Primary Geographic Jurisdiction Kentucky
LCD Title High Sensitivity C-Reactive Protein (hsCRP) Testing	Oversight Region Region I
Contractor's Determination Number L26445	Original Determination Effective Date For services performed on or after 04/30/2011

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Original Determination Ending Date
Revision Effective Date For services performed on or after 06/18/2011
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 §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.

Code of Federal Regulations:

42 CFR Section 410.32 indicates that diagnostic tests may only be ordered by treating the physician (or other treating practitioner acting within the scope of his or her license and Medicare requirements) **who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician (or other qualified non-physician provider) who is treating the beneficiary are not reasonable and necessary (see Sec. 411.15(k)(1) of this chapter).**

CMS Publications:

CMS Pub. 100-04 *Medicare Claims Processing Manual*, Chapter 4 provides information on the Outpatient Prospective Payment System (OPPS).

CMS Publication 100-04, *Medicare Claims Processing Manual*, Chapter 16:

- 30.3 Method of Payment for Clinical Laboratory Tests – Place of Service Variation
- 40.3 Hospital Billing Under Part B (for laboratory services)
 - 40.3.1 Critical Access Hospital (CAH) Outpatient Laboratory Service
- 40.4 Special Skilled Nursing Facility (SNF) Billing Exceptions for Laboratory Tests
 - 40.4.1 Which Contractor to Bill for Laboratory Services Furnished to a Medicare Beneficiary in a Skilled Nursing Facility (SNF)
- 40.5 Rural Health Clinic (RHC) Billing (for laboratory services)
- 50.3.2 Hospital Laboratory Services Furnished to Non hospital Patients
- 70.3 Verifying CLIA Certification
- 90 Automated Profile Tests and Organ/Disease Oriented Panels

CMS Publication 100-04; *Medicare Claims Processing Manual*, Chapter 18:

- 100 Cardiovascular Disease Screening

CMS Publication 100-04; *Medicare Claims Processing Manual*, Chapter 30:

- 20.2.1 Denials for Which the Limitation on Liability Provision Does Not Apply - Categorical Denials
 - 50 Form CMS-R-131 Advance Beneficiary Notice (ABN)
 - 90 Form CMS-20007-Notice of Exclusions from Medicare Benefits (NEMBs)

CMS Manual System; Pub. 100-20, One-Time Notification, Transmittal 408. Change Request #3411, December 17, 2004, Cardiovascular Disease Screening. This recent extension of cardiovascular disease screening benefits does not include high sensitivity.

Indications and Limitations of Coverage and/or Medical Necessity

Abstract:

A role for inflammation has been established in theories describing the atherosclerotic disease process. The use of markers of inflammation to improve the diagnosis and management of patients with atherosclerotic disease is less clear and continues to be studied and debated.

High-sensitivity C-reactive protein (hsCRP) is a marker of inflammation with detection levels as low as 0.07 mg/L in the blood. Prior to the development of the high-sensitivity assays, the lower limit of detection of CRP was 3 mg/L. Levels greater than 10 mg/L are not useful for risk stratification.

The 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)” was published in May 2001. The American Heart Association (AHA) and the Centers for Disease Control and Prevention (CDC) convened a workshop in March 2002 entitled, “CDC/AHA Workshop on Inflammatory Markers and Cardiovascular Disease: Applications to Clinical and Public Health Practice.” Building upon the NCEP guidelines, the AHA/CDC report made recommendations for limited high-sensitivity C-reactive protein testing in the assessment and management of coronary heart disease (CHD) which were influential in the development of this policy.

Indications:

Testing for hsCRP will be considered medically necessary for the assessment of coronary heart disease (CHD) risk assessment and management when ALL of the following criteria are met:

- The patient is considered at intermediate risk (10-20% of CHD per 10 years) using the NCEP Adult Treatment Panel III (ATP III) guidelines.
- The hsCRP level is being obtained to determine whether lipid-lowering pharmacologic therapy is needed for the primary prevention of CHD.
- The patient is metabolically stable and without obvious inflammatory or infectious conditions.

The test may be obtained two times, optimally two weeks apart, to obtain an average level. Results of > 10 mg/L should be discarded and not repeated for at least two weeks after the source of infection or inflammation has been identified and cleared.

Limitations:

Testing will be denied as not medically necessary for any of the following:

- To screen the general population for CHD or other atherosclerotic disease risk;
- To determine whether life-style changes or discontinuation of tobacco use should occur to reduce the risk of CHD;
- To assess and/or manage established CHD or other established atherosclerotic disease;
- To monitor statin or other lipid-lowering therapy.

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 CIGNA Government Services 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.

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 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.

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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.

013x	Hospital Outpatient
071x	Clinic - Rural Health
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.

030X	Laboratory - General Classification
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**CPT/HCPCS Codes
GroupName**

86141	C-REACTIVE PROTEIN; HIGH SENSITIVITY (HSCRP)
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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 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.

272.0	PURE HYPERCHOLESTEROLEMIA
272.1	PURE HYPERGLYCERIDEMIA
272.2	MIXED HYPERLIPIDEMIA
272.3	HYPERCHYLOMICRONEMIA
272.4	OTHER AND UNSPECIFIED HYPERLIPIDEMIA

Diagnoses that Support Medical Necessity

Not applicable

ICD-9 Codes that DO NOT Support Medical Necessity

Use of any ICD-9-CM code not listed in the "ICD-9-CM Codes that Support Medical Necessity" section of this LCD will be denied. In addition, the following ICD-9 CM codes are specifically listed as not supporting medical necessity for emphasis and to avoid claim payment errors.

V71.7	OBSERVATION FOR SUSPECTED CARDIOVASCULAR DISEASE
V81.0	SCREENING FOR ISCHEMIC HEART DISEASE
V81.2	SCREENING FOR OTHER AND UNSPECIFIED CARDIOVASCULAR CONDITIONS
V82.9	SCREENING FOR UNSPECIFIED CONDITION

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.

Appendices Not applicable

Utilization Guidelines The measurement of hsCRP should only be performed in a metabolically stable patient without obvious inflammatory or infectious conditions. The test may be performed twice (averaging results), optimally two weeks apart with the average expressed in mg/L. A result of >10mg/L should be discarded and not repeated for at least two weeks after the source of infection or inflammation has been identified and cleared. It is expected that no more than two tests per beneficiary will be performed with only an occasional beneficiary needing a third test due to one level >10.0 mg/L needing to be discarded. Testing will be limited to three tests per beneficiary lifetime.

Use of hsCRP testing for monitoring lipid or other therapy is not considered necessary and will be denied.

Sources of Information and Basis for Decision

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

Carrier Advisory Committee

CIGNA Government Services (CGS) and other Medicare contractors' Local Coverage Determinations.

Agmon Y, Khandheria BK, Meissner I, et al. C-reactive protein and atherosclerosis of the thoracic aorta. *LArch Intern Med.* 2004;164:1781-1787.

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Blue Cross Blue Shield Technology Evaluation Center. Special report: high-sensitivity C-reactive protein measurement for coronary heart disease risk stratification. Assessment Program Volume 17, No. 23, May 2003.

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Danish J, Wheeler, JG, Hirschfield GM, et al. C-reactive protein and other circulating markers of inflammation in the prediction of coronary heart disease. *N Engl J Med.* 2004;350:1387-1397.

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Pearson TA, Mensah GA, Alexander RW, et al. AHA/CDC Scientific Statement. Markers of inflammation and cardiovascular disease. Application to clinical and public health practice. A statement for healthcare professionals from the Centers for Disease Control and Prevention and the American Heart Association. *Circ.* 2003;107:499-511.

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Ridker PM, Rifai N, Rose L, Buring JE, Cook NR. Comparison of C-reactive protein and low-density lipoprotein cholesterol levels in the prediction of first cardiovascular events. *N Engl J Med.* 2004;347:1557-11565.

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Advisory Committee Meeting Notes

Start Date of Comment Period

End Date of Comment Period

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Start Date of Notice Period

Revision History Number R1

Revision History Explanation Revision#:R1

Revision Effective date: 06/18/11

Revision Explanation: Added MAC Part B Contractor # 15202 to all MAC Part B Contractor # 15102 LCDs. Contractor 15202 will be part of the Jurisdiction 15 MAC Contract as of June 18, 2011.

This LCD was converted from L26445 for Jurisdiction 15 A/B MAC on 04/30/2011.

All prior notes were retained with the previous carriers version that has been archived in the Medicare Coverage Database.

Reason for Change

Last Reviewed On Date 02/09/2011

Related Documents

This LCD has no Related Documents.

LCD Attachments

There are no attachments for this LCD.

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All Versions

Updated on 05/06/2011 with effective dates 06/18/2011 - N/A

Updated on 05/05/2011 with effective dates 06/18/2011 - N/A

Updated on 02/09/2011 with effective dates 04/30/2011 - N/A

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