LCD L30256 - C-Reactive Protein High Sensitivity Testing (hsCRP)

Contractor Information

Contractor Name:	Contractor Number(s):	Contractor Type:
Novitas Solutions, Inc.	12501, 12101, 12102, 12201, 12202, 12301, 12302, 12401, 12402, 12901, 12502	MAC Part A & B

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LCD Information

Document Information

LCD ID Number	**Primary Geographic Jurisdiction**
L30256	Pennsylvania, Maryland, District of Columbia, New Jersey, Delaware
LCD Title	**Oversight Region**
C-Reactive Protein High Sensitivity Testing (hsCRP)	Central Office
Contractor's Determination Number	**Original Determination Effective Date**
L30256	For services performed on or after 10/28/2009
AMA CPT/ADA CDT Copyright Statement	**Original Determination Ending Date**
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	Revision Effective Date
	For services performed on or after 07/09/2012
	Revision Ending Date
	N/A

CMS National Coverage Policy

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.

Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.

Indications and Limitations of Coverage 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.

C-reactive protein, (CRP), is a nonspecific, acute-phase reactant produced in response to tissue injury, inflammation or infection. As an acute phase reactant, concentrations rise rapidly and half-life is short. Studies have shown that chronic, low-grade inflammation contributes to atherogenesis and the development of coronary artery disease (CAD). Inflammatory changes lead to progressive disease, which culminates in plaque instability, rupture, thrombosis, and myocardial infarction (MI).

CRP testing, CPT code *86140*, is eligible for coverage as a diagnostic test for the detection and evaluation of infection, tissue injury, and inflammatory disease. This CPT code, *86140*, is not to be used in place of CPT code *86141*, which represents high sensitivity C-reactive protein (hsCRP) testing and the subject of this policy.

A high sensitivity C-reactive protein (hsCRP) assay measures low levels of CRP, which allows for measurement of conditions indicative of chronic, low-grade inflammation. The stimulus for the rise in serum CRP in CAD remains undetermined, although it may result from local inflammation within atheromatous plaques, from a systemic or local inflammation or infection elsewhere in the body that contributes to atherogenesis, or to unrelated conditions. Increased CRP may reflect plaque instability and an increased risk for a CAD event. Published literature presents strong evidence to refute the hypothesis that CRP itself has a causative effect on coronary heart disease.

High-sensitivity assays can measure levels as low as 0.175 mg/L, which may be associated with CAD. HsCRP assays are based on nephelometric analysis of antigen-antibody complexes using monoclonal antibodies with sufficient sensitivity to detect low levels of CRP.

This contractor will consider high-sensitivity C-reactive protein (hsCRP) testing reasonable and necessary when ALL of the following criteria are met:

- When the hsCRP would add substantial incremental information in the decision making process to optimize/maximize lipid lowering pharmacologic therapy, (e.g., use of statins), in a patient who has been identified as being at intermediate risk for CAD (10-year risk of coronary heart disease between 10-20% per the ATPIII Guidelines). This is to be used for a one time decision point and is not intended to monitor therapy.
- The test is performed in patients considered to be metabolically stable and without obvious inflammatory or infectious conditions.

The American Heart Association (AHA) recommends the following cutpoints for hsCRP corresponding to three levels of risk:

- Low risk < 1.0 mg/L
- Average risk > 1.0 to < 3.0 mg/L
- High risk > 3.0 mg/L

Limitations

Medicare does not provide coverage for routine screening performed without a relationship to the evaluation or treatment of a symptom, sign, illness or injury. If high sensitivity C-reactive protein (hsCRP) testing is performed for cardiovascular risk assessment, in the

absence of signs or symptoms of illness or injury, then the service will be denied as not reasonable and necessary.

Medicare does not cover hsCRP testing as a screening test for the general population or for monitoring response to therapy.

Although hsCRP is commonly elevated in inflammatory conditions (e.g., rheumatic fever, rheumatoid arthritis, systemic vasculitis, myocardial infarction, acute pancreatitis), measurements in these illnesses is not appropriate and is considered not reasonable and necessary.

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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
022x	Skilled Nursing - Inpatient (Medicare Part B only)
023x	Skilled Nursing - Outpatient
072x	Clinic - Hospital Based or Independent Renal Dialysis Center
083x	Ambulatory Surgery Center
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.

030X	Laboratory - General Classification

CPT/HCPCS Codes

Italicized and/or quoted material is excerpted from the American Medical Association, *Current Procedural Terminology (CPT)* codes.

86141	C-REACTIVE PROTEIN; HIGH SENSITIVITY (HSCRP)

ICD-9 Codes that Support Medical Necessity

For CPT/HCPCS code *86141*:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-9-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

272.0	PURE HYPERCHOLESTEROLEMIA
272.1	PURE HYPERGLYCERIDEMIA
272.2	MIXED HYPERLIPIDEMIA
272.3	HYPERCHYLOMICRONEMIA
272.4	OTHER AND UNSPECIFIED HYPERLIPIDEMIA
414.01	CORONARY ATHEROSCLEROSIS OF NATIVE CORONARY ARTERY
V49.89*	OTHER SPECIFIED CONDITIONS INFLUENCING HEALTH STATUS

*Use ICD-9-CM code V49.89 for patients at intermediate risk for CAD who do not have elevated lipids (i.e., do not meet criteria to use ICD-9-CM codes 272.0-272.4).

Diagnoses that Support Medical Necessity

Not Applicable

ICD-9 Codes that DO NOT Support Medical Necessity

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

Diagnoses that DO NOT Support Medical Necessity

Not Applicable

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Other Information

Documentation Requirements

1. All documentation must be maintained in the patient's medical record and 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 record must include the physician or non-physician practitioner responsible for and providing the care of the patient.

3. The submitted medical record must support the use of the selected ICD-9-CM code(s). The submitted CPT/HCPCS code must describe the service performed.

4. The ordering physician should retain in the patient's medical record, history and physical examination notes documenting evaluation and management of one of the Medicare covered conditions/diagnoses, with relevant clinical signs/symptoms or abnormal laboratory test results, appropriate to one of the covered indications.

5. The patient's clinical record should further indicate changes/alterations in medications or management prescribed for the treatment of the patient.

6. There must be an attending/treating physician's order for each test documented in the patient's medical/clinical record.