

Local Coverage Determination (LCD): C-Reactive Protein High Sensitivity Testing (hsCRP) (L34856)

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
Novitas Solutions, Inc.	A and B MAC	04111 - MAC A	J - H	Colorado
Novitas Solutions, Inc.	A and B MAC	04112 - MAC B	J - H	Colorado
Novitas Solutions, Inc.	A and B MAC	04211 - MAC A	J - H	New Mexico
Novitas Solutions, Inc.	A and B MAC	04212 - MAC B	J - H	New Mexico
Novitas Solutions, Inc.	A and B MAC	04311 - MAC A	J - H	Oklahoma
Novitas Solutions, Inc.	A and B MAC	04312 - MAC B	J - H	Oklahoma
Novitas Solutions, Inc.	A and B MAC	04411 - MAC A	J - H	Texas
Novitas Solutions, Inc.	A and B MAC	04412 - MAC B	J - H	Texas
Novitas Solutions, Inc.	A and B MAC	04911 - MAC A	J - H	Colorado New Mexico Oklahoma Texas
Novitas Solutions, Inc.	A and B MAC	07101 - MAC A	J - H	Arkansas
Novitas Solutions, Inc.	A and B MAC	07102 - MAC B	J - H	Arkansas
Novitas Solutions, Inc.	A and B MAC	07201 - MAC A	J - H	Louisiana
Novitas Solutions, Inc.	A and B MAC	07202 - MAC B	J - H	Louisiana
Novitas Solutions, Inc.	A and B MAC	07301 - MAC A	J - H	Mississippi
Novitas Solutions, Inc.	A and B MAC	07302 - MAC B	J - H	Mississippi
Novitas Solutions, Inc.	A and B MAC	12101 - MAC A	J - L	Delaware
Novitas Solutions, Inc.	A and B MAC	12102 - MAC B	J - L	Delaware
Novitas Solutions, Inc.	A and B MAC	12201 - MAC A	J - L	District of Columbia
Novitas Solutions, Inc.	A and B MAC	12202 - MAC B	J - L	District of Columbia
Novitas Solutions, Inc.	A and B MAC	12301 - MAC A	J - L	Maryland
Novitas Solutions, Inc.	A and B MAC	12302 - MAC B	J - L	Maryland
Novitas Solutions, Inc.	A and B MAC	12401 - MAC A	J - L	New Jersey
Novitas Solutions, Inc.	A and B MAC	12402 - MAC B	J - L	New Jersey
Novitas Solutions, Inc.	A and B MAC	12501 - MAC A	J - L	Pennsylvania
Novitas Solutions, Inc.	A and B MAC	12502 - MAC B	J - L	Pennsylvania
Novitas Solutions, Inc.	A and B MAC	12901 - MAC A	J - L	District of Columbia Delaware Maryland New Jersey Pennsylvania

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LCD Information

Document Information

LCD ID
L34856

Original Effective Date
For services performed on or after 10/01/2015

Original ICD-9 LCD ID
[L30256](#)

Revision Effective Date
For services performed on or after 10/01/2016

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

Revision Ending Date
N/A

Proposed LCD in Comment Period
N/A

Retirement Date
N/A

Source Proposed LCD
N/A

Notice Period Start Date
02/19/2016

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04/06/2016

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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. 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 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 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 rules.

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.
- 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.

Coverage Indications, Limitations, and/or Medical Necessity

Notice: It is not appropriate to bill Medicare for services that are not covered (as described by this entire LCD) as if they are covered. When billing for non-covered services, use the appropriate modifier.

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.

Notice: This LCD imposes frequency limitations as well as diagnosis limitations that support diagnosis to procedure code automated denials. 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. Please refer to the "Utilization Guidelines" section for an outline of the frequency limitations.

As published in CMS IOM 100-08, Chapter 13, Section 13.5.1, in order to be covered under Medicare, a service shall be reasonable and necessary. When appropriate, contractors shall describe the circumstances under which the proposed LCD for the service is considered reasonable and necessary under Section 1862 (a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective.
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, that meet the requirements of the Clinical Trials NCD are considered reasonable and necessary).
- Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member.
 - Furnished in a setting appropriate to the patient's medical needs and condition.
 - Ordered and furnished by qualified personnel.
 - One that meets, but does not exceed, the patient's medical needs.
 - At least as beneficial as an existing and available medically appropriate alternative.

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

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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.

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.

Note: The contractor has identified the Bill Type and Revenue Codes applicable for use with the CPT/HCPCS codes included in this LCD. Providers are reminded that not all CPT/HCPCS codes listed can be billed with all Bill Type and/or Revenue Codes listed. CPT/HCPCS codes are required to be billed with specific Bill Type and Revenue Codes. Providers are encouraged to refer to the CMS Internet-Only Manual (IOM) Pub. 100-04, Claims Processing Manual, for further guidance.

030X Laboratory - General Classification

CPT/HCPCS Codes

Group 1 Paragraph: Note: Providers are reminded to refer to the long descriptors of the CPT codes in their CPT Book.

Group 1 Codes:

86141 C-reactive protein hs

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph: 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-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

Group 1 Codes:

ICD-10 Codes

Description

E78.00	Pure hypercholesterolemia, unspecified
E78.01	Familial hypercholesterolemia
E78.1	Pure hyperglyceridemia
E78.2	Mixed hyperlipidemia
E78.3	Hyperchylomicronemia
E78.4	Other hyperlipidemia
I25.10	Atherosclerotic heart disease of native coronary artery without angina pectoris
Z74.09*	Other reduced mobility
Z78.9*	Other specified health status

Group 1 Medical Necessity ICD-10 Codes Asterisk Explanation: *Use ICD-10-CM code Z74.09 and Z78.9 for patients at intermediate risk for CAD who do not have elevated lipids (i.e., do not meet criteria to use ICD-10-CM codes E78.00-E78.4).

ICD-10 Codes that DO NOT Support Medical Necessity

Group 1 Paragraph: All those not listed under the "ICD-10 Codes that Support Medical Necessity" section of this policy.

Group 1 Codes: N/A

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

[General Information](#)

Associated 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 submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.

4. The medical record documentation must support the medical necessity of the services as directed in this policy.
5. 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 clinical signs/symptoms or abnormal laboratory test results, appropriate to one of the covered indications.
6. The patient's clinical record should further indicate changes/alterations in medications or management prescribed for the treatment of the patient.
7. There must be an attending/treating physician's order for each test documented in the patient's medical/clinical record.

Appendices

N/A

Utilization Guidelines

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

Generally, the measurement of hsCRP markers is performed twice (averaging results), optimally two weeks apart and fasting or nonfasting, with the average expressed in mg/L, in metabolically stable patients.

It is considered reasonable and necessary to perform no more than 3 hsCRP services per patient lifetime.

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 and Basis for Decision

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

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O'Keefe JH, Carter MD, Lavie CJ. Primary and Secondary Prevention of Cardiovascular Diseases: A Practical Evidence-Based Approach. *Mayo Clin Proc* 2009;84(8):741-757.

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Other Contractor(s)' Policies

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[Revision History Information](#)

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
10/01/2016	R4	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 E78.0. The following ICD-10 code(s) have been added to the LCD: Group 1 codes E78.00 and E78.01. The Group 1 asterisk note has been revised to reflect the ICD-10 updated codes.	<ul style="list-style-type: none">• Revisions Due To ICD-10-CM Code Changes
04/07/2016	R3	Added standard language to the Utilization Guidelines section.	<ul style="list-style-type: none">• Other (Clarification)
04/07/2016	R2	LCD posted for notice on 02/19/2016 to become effective 04/07/2016.	<ul style="list-style-type: none">• Creation of Uniform LCDs With Other MAC Jurisdiction
		09/17/2015 DL34856 Draft LCD posted for Comments.	
10/01/2015	R1		

**Revision
History
Date**

**Revision
History
Number**

Revision History Explanation

**Reason(s) for
Change**

LCD revised and published on 12/10/2015 effective for dates of service on and after 10/01/2015. ICD-10 codes I25.110; I25.111; I25.118 and I25.119 have been added as covered diagnoses.

- Other (Additional codes added to policy to allow for higher specificity.)

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[Associated Documents](#)

Attachments N/A

Related Local Coverage Documents LCD(s) [DL34856](#) - (MCD Archive Site)

Related National Coverage Documents N/A

Public Version(s) Updated on 09/22/2016 with effective dates 10/01/2016 - N/A Some older versions have been archived. Please visit the [MCD Archive Site](#) to retrieve them. [Back to Top](#)

[Keywords](#)

N/A Read the [LCD Disclaimer](#) [Back to Top](#)