

LCD for C-Reactive Protein High Sensitivity Testing (hsCRP) (L34856)

Contractor Information

Contractor Name: Novitas Solutions, Inc.

Contractor Number: 12502

Contractor Type: MAC B

LCD Information

LCD ID Number: L34856 **Status:** A-Approved

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

Geographic Jurisdiction: Pennsylvania [Other Jurisdictions](#)

Original Determination Effective Date: 10/01/2015

Original Determination Ending Date:

Revision Effective Date: 10/01/2018

Revision End Date:

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 hsCRP testing. 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 for hsCRP testing 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. 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 100-04, *Medicare Claims Processing Manual*
 - Chapter 16, Laboratory Services
 - Chapter 23, Section 40: Clinical Diagnostic Laboratory Fee Schedule

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.

Federal Register References:

- 42 CFR, Section 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

Indications and Limitations of Coverage 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.

History/Background and/or General Information

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.

Covered Indications

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

1. 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.
2. 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 less than 1.0 mg/L
- Average risk greater than 1.0 to less than 3.0 mg/L
- High risk greater than 3.0 mg/L

Limitations

1. 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.
2. Medicare does not cover hsCRP testing as a screening test for the general population or for monitoring response to therapy.
3. 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.

For frequency limitations, please refer to the Utilization Guidelines section below.

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.

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.

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

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.

12	Hospital Inpatient (Medicare Part B only)
13	Hospital Outpatient
14	Hospital - Laboratory Services Provided to Non-patients
22	Skilled Nursing - Inpatient (Medicare Part B only)
23	Skilled Nursing - Outpatient
72	Clinic - Hospital Based or Independent Renal Dialysis Center
83	Ambulatory Surgery Center
85	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.

0309	Laboratory - Other Laboratory
0303	Laboratory - Renal Patient (Home)
0302	Laboratory - Immunology
0300	Laboratory - General Classification
0301	Laboratory - Chemistry
0307	Laboratory - Urology
0306	Laboratory - Bacteriology & Microbiology
0305	Laboratory - Hematology
0304	Laboratory - Non-Routine Dialysis

CPT/HCPCS Codes:

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

86141 C-REACTIVE PROTEIN; HIGH SENSITIVITY (HSCRIP)

ICD-10 Codes that Support Medical Necessity:

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.

Medicare is establishing the following limited coverage for CPT/HCPCS code 86141:

E78.00	Pure hypercholesterolemia, unspecified
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E78.01	Familial hypercholesterolemia
E78.1	Pure hyperglyceridemia
E78.2	Mixed hyperlipidemia
E78.3	Hyperchylomicronemia
E78.49	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

*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-E78.3 or E78.49).

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 stated 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.

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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Cushman M, Arnold AM, Psaty BM, et al. C-reactive protein and the 10-year incidence of coronary heart disease in older men and women. *Circulation*. 2005; 112:25-31.

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Other Contractor(s)' Policies

Contractor Medical Directors

Start Date of Notice Period 02/19/2016

Revision History Information

Revision History Date	Revision History Number	Revision History Explanation
10/01/2018	R6	<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 code has been deleted and therefore removed from the LCD: E78.4. The following ICD-10-CM code has been added to the LCD Group 1 codes: E78.49.</p> <p>The Group 1 asterisk note has been revised to reflect the ICD-10 code updates.</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>

05/10/2018	R5	<p>LCD revised and published on 05/10/2018 to add sources submitted with a reconsideration request for the addition of multiple ICD-10 codes. All literature was reviewed. No changes to the policy were made based on the reconsideration request. IOM citations for diagnostic laboratory services added per annual review.</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 on the LCD are applicable as noted in this policy.</p>
10/01/2016	R4	<p>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.</p>
04/07/2016	R3	<p>Added standard language to the Utilization Guidelines section.</p>
04/07/2016	R2	<p>LCD posted for notice on 02/19/2016 to become effective 04/07/2016.</p> <p>09/17/2015 DL34856 Draft LCD posted for Comments.</p>
10/01/2015	R1	<p>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.</p>

All information on this web site is compiled directly from information obtained from the Center for Medicare and Medicaid Services (CMS) and from its Contractors.

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