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

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CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Novitas Solutions, Inc.	A and B MAC	12901 - MAC A	J - L	Delaware District of Columbia Maryland New Jersey Pennsylvania

Original Effective Date

LCD Information

Document Information

LCD ID

L34856 For services performed on or after 10/01/2015 **LCD** Title **Revision Effective Date** For services performed on or after 11/07/2019 C-Reactive Protein High Sensitivity Testing (hsCRP) **Proposed LCD in Comment Period Revision Ending Date** N/A N/A Source Proposed LCD **Retirement Date** DL34856 N/A **Notice Period Start Date** AMA CPT / ADA CDT / AHA NUBC Copyright Statement 02/19/2016 CPT codes, descriptions and other data only are copyright 2018 American Medical Association. All Rights **Notice Period End Date** 04/06/2016 Reserved. Applicable FARS/HHSARS apply. Current Dental Terminology © 2018 American Dental Association. All rights reserved. Copyright © 2019, the American Hospital Association, Chicago, Illinois. Reproduced with permission. No portion of the AHA copyrighted materials contained within this publication may be copied without the express written consent of the AHA. AHA copyrighted materials including the UB-04 codes and descriptions may not be removed, copied, or utilized within any software, product, service, solution or derivative work without the written consent of the AHA. If an entity wishes to utilize any AHA materials, please contact the AHA at 312-893-6816. Making copies or utilizing the content of the UB-04 Manual, including the codes and/or descriptions, for internal purposes, resale and/or to be

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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 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 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.
- 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.

Federal Register References:

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

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

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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 is eligible for coverage as a diagnostic test for the detection and evaluation of infection, tissue injury, and inflammatory disease. High sensitivity C-reactive protein (hsCRP) testing is 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:

- 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

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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.
- 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.

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

Notice: 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. Refer to Billing and Coding: C-Reactive Protein High Sensitivity Testing (hsCRP), A56643, for applicable CPT codes and diagnosis codes.

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

Summary of Evidence

N/A

Analysis of Evidence (Rationale for Determination)

N/A

General Information

Associated Information

Refer to the Local Coverage Article: Billing and Coding: C-Reactive Protein High Sensitivity Testing (hsCRP), A56643, for all coding information.

Documentation Requirements

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- 1. All documentation must be maintained in the patient's medical record and made available to the contractor upon request.
- 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 medical record documentation must support the medical necessity of the services as stated in this policy.
- 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 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.

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

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

Other Contractor(s)' Policies

Contractor Medical Directors

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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
11/07/2019	R8	LCD revised and published on 11/07/2019. Consistent with CMS Change Request 10901, the entire coding section has been removed from the LCD and placed into the related Billing and Coding Article, A56643. All CPT codes and coding information within the text of the LCD has been placed in the Billing and Coding Article.	 Other (CMS Change Request 10901)

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
06/27/2019	R7	LCD revised and published on 06/27/2019. Consistent with Change Request (CR) 10901 CMS IOM language has been removed from the LCD. All CPT and ICD-10 codes have been removed from the LCD and placed in the related Billing and Coding Article, A56643. The references have been moved to the Bibliography section and a link to A56643 has been added as a related document. There has been no change in coverage with this LCD revision.	 Other (Change in LCD process per CMS CR 10901)
10/01/2018	R6	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. The Group 1 asterisk note has been revised to reflect the ICD-10 code updates. 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.	 Revisions Due To ICD-10-CM Code Changes
05/10/2018	R5	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. 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.	 Other (Reconsideration Request and Annual Review)
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	 Revisions Due To ICD-10-CM Code Changes

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		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.	
04/07/2016	R3	Added standard language to the Utilization Guidelines section.	Other (Clarification)
04/07/2016	R2	LCD posted for notice on 02/19/2016 to become effective 04/07/2016. 09/17/2015 DL34856 Draft LCD posted for Comments.	 Creation of Uniform LCDs With Other MAC Jurisdiction
10/01/2015	R1	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.)

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A56643 - Billing and Coding: C-Reactive Protein High Sensitivity Testing (hsCRP)

LCD(s)

DL34856

- (MCD Archive Site)

Related National Coverage Documents

N/A

Public Version(s)

Updated on 11/01/2019 with effective dates 11/07/2019 - N/A Updated on 06/20/2019 with effective dates 06/27/2019 - 11/06/2019 Updated on 10/19/2018 with effective dates 10/01/2018 - 06/26/2019 Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

Keywords

N/A