Local Coverage Determination (LCD):
High Sensitivity C-Reactive Protein (hsCRP) (L33908)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD website.

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**Contractor Information**

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<th>Contract Type</th>
<th>Contract Number</th>
<th>Jurisdiction</th>
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<td>J - N</td>
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**Document Information**

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<th>LCD ID</th>
<th>Original Effective Date</th>
<th>For services performed on or after 10/01/2015</th>
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<td>L33908</td>
<td><strong>Original ICD-9 LCD ID</strong> L29191</td>
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<td><strong>Original Effective Date</strong></td>
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**Source Proposed LCD**

N/A

**LCD Title**

High Sensitivity C-Reactive Protein (hsCRP)

**Proposed LCD in Comment Period**

N/A

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Recent 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). Increasing recognition of the inflammatory component of atherogenesis provides the biological plausibility for the use of inflammatory markers as prognostic indicators of atherosclerotic complications.

Increased serum levels of C-reactive protein (CRP), an inflammatory biomarker, have been linked to an increased risk of myocardial infarction, stroke, peripheral arterial disease, and sudden cardiac death even in the absence of hyperlipidemia. CRP is a nonspecific, acute-phase reactant produced in response to tissue injury, inflammation or infection. CRP is secreted by hepatocytes, where its synthesis is regulated by cytokines. 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.

The standard CRP assays have limits of measuring acute-phase detection of 3.0-5.0 mg/L and lack the sensitivity required to detect slight elevations that occur in CAD. 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.

The hsCRP results, along with The Framingham Heart Study Risk Assessment (a tool which considers gender, age, total cholesterol, HDL cholesterol, systolic blood pressure, antihypertensive medications, family history and smoking risks) provides cardiac prognostic information. However, hsCRP and LDL cholesterol levels are minimally correlated.

High-sensitivity C-reactive protein (hsCRP) testing will be considered medically reasonable and necessary for the assessment of CAD risk when ALL of the following criteria are met:

- When the hsCRP would add substantial incremental information in the decision making process to optimize/maximize current lipid lowering pharmacologic therapy 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
Routine screening performed without a relationship to the evaluation or treatment of a symptom, sign, illness or injury is not covered. 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 or medically necessary.
Testing for hsCRP as a screening test for the general population or for monitoring response to therapy is not covered.

Commonly, hsCRP is elevated in inflammatory conditions (e.g., rheumatic fever, rheumatoid arthritis, systemic vasculitis, myocardial infarction, acute pancreatitis) and are not considered medically reasonable and necessary for purposes of this LCD.

Summary of Evidence
N/A

Analysis of Evidence (Rationale for Determination)
N/A

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.

| 999x | Not Applicable |

**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.

| 99999 | Not Applicable |

**CPT/HCPCS Codes**

**Group 1 Paragraph:** N/A

**Group 1 Codes:**

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<th>Code</th>
<th>Description</th>
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<tr>
<td>86141</td>
<td>C-REACTIVE PROTEIN; HIGH SENSITIVITY (HSCRP)</td>
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**ICD-10 Codes that Support Medical Necessity**

**Group 1 Paragraph:** N/A

**Group 1 Codes:**

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<th>ICD-10 CODE</th>
<th>DESCRIPTION</th>
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<tr>
<td>E78.00</td>
<td>Pure hypercholesterolemia, unspecified</td>
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<tr>
<td>E78.01</td>
<td>Familial hypercholesterolemia</td>
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<tr>
<td>E78.1</td>
<td>Pure hyperglyceridemia</td>
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<tr>
<td>E78.2</td>
<td>Mixed hyperlipidemia</td>
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<td>E78.3</td>
<td>Hyperchylomicronemia</td>
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<td>E78.5</td>
<td>Hyperlipidemia, unspecified</td>
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<td>I25.10</td>
<td>Atherosclerotic heart disease of native coronary artery without angina pectoris</td>
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<td>Z74.09*</td>
<td>Other reduced mobility</td>
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<td>Z78.9*</td>
<td>Other specified health status</td>
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**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-E78.49).*

**ICD-10 Codes that DO NOT Support Medical Necessity**

**ICD-10 Additional Information**
N/A
General Information

Associated Information
Documentation Requirements

Medical record documentation maintained by the ordering/referring physician/qualified nonphysician practitioner must indicate the medical necessity for performing the test and the test results. In addition, if the service exceeds the frequency parameter listed in this LCD, documentation of medical necessity must be submitted upon request. This information is usually found in the history and physical, office/progress notes, or test results.

If the provider of the service is other than the ordering/referring physician/nonphysician practitioner, that provider must maintain a copy of test results, along with copies of the ordering/referring physician/nonphysician practitioner’s order for the test. The clinical indication/medical necessity for the test must be indicated in the order for the test.

Documentation should support the criteria for coverage as set forth in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this LCD and should reflect how the results of this test will be used in the patient’s plan of care.

Utilization Guidelines

Generally, the measurement of hsCRP markers may be performed twice (averaging results), optimally two weeks apart and fasting or nonfasting, with the average expressed in mg/L, in metabolically stable patients. If an average CRP level of >10.0 mg/L is found on two tests performed 2 weeks apart, a third test may be performed after ruling out possible infectious or inflammatory causes for the increase (AHA/CDC Recommendation).

It is expected that these services would be performed as indicated by current medical literature and/or standards of practice. When services are performed in excess of established parameters, they may be subject to review for medical necessity.

Sources of Information

First Coast Service Options, Inc. reference LCD number – L29437


**Bibliography**

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<th>REVISION HISTORY DATE</th>
<th>REVISION HISTORY NUMBER</th>
<th>REVISION HISTORY EXPLANATION</th>
<th>REASON(S) FOR CHANGE</th>
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| 10/01/2018            | R3                      | Revision Number: 3
Publication: September 2018 Connection LCR B2018-017
Explanation of Revision: Based on CR 10847 (Annual 2019 ICD-10-CM Update) the LCD was revised. Added ICD-10-CM diagnosis code E78.49. Deleted ICD-10-CM diagnosis code E78.4. In addition, the asterisked statement under the “ICD-10 Codes that Support Medical Necessity” section of the LCD was revised to include ICD-10-CM diagnosis code E78.49. The effective date of this revision is based on date of service. 10/01/2018: 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 and therefore not all the fields included on the LCD are applicable as noted in this policy. | Revisions Due To ICD-10-CM Code Changes |
| 07/10/2018            | R2                      | Revision Number: 2
Publication: July 2018 Connection LCR B2018-013
Explanation of Revision: Based on a LCD reconsideration request, the LCD was revised to add, ICD-10-CM diagnosis codes Z74.09, Z78.9 and I25.10 and the asterisked explanation language “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)” to the “ICD-10 Codes that Support Medical Necessity” section of the LCD for CPT code 86141. Also, the “Sources of Information and Basis for Decision” section of the LCD was updated. The effective date of this revision is based on date of service. 07/10/2018: 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 and therefore not all the fields included on the LCD are applicable as noted in this policy. | Reconsideration Request |
| 10/01/2016            | R1                      | Revision Number: 1
Publication: October 2016 Connection LCR A/B2016-097
Explanation of Revision: Based on CR 9677 (Annual 2017 ICD-10-CM Update) the LCD was revised. Deleted | Revisions Due To ICD-10-CM Code Changes |
ICD-10-CM diagnosis code E78.0. Added ICD-10-CM diagnosis codes E78.00 and E78.01. The effective date of this revision is based on date of service.

Associated Documents

Attachments
N/A

Related Local Coverage Documents
N/A

Related National Coverage Documents
N/A