LCD Database ID Number

L33908

Contractor Name

First Coast Service Options, Inc.

Contractor Number

09102 – Florida
09202 – Puerto Rico
09302 – Virgin Islands

Contractor Type

MAC – Part B

LCD Title

High Sensitivity C-Reactive Protein (hsCRP)

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Language quoted from CMS National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals are italicized throughout the Local Coverage Determination (LCD). NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, italicized text represents quotation from one or more of the following CMS sources:

N/A
Primary Geographic Jurisdiction

Florida
Puerto Rico/Virgin Islands

Oversight Region

Region I

Original Determination Effective Date

10/01/2015

Original Determination Ending Date

N/A

Revision Effective Date

10/01/2016

Revision Ending Date

09/30/2016

Indications and Limitations of Coverage and/or Medical Necessity

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.

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 policy.

**CPT/HCPCS Codes**

86141 C-reactive protein; high sensitivity (hsCRP)

**ICD-10 Codes that Support Medical Necessity**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>E78.00</td>
<td>Pure hypercholesterolemia, unspecified</td>
</tr>
<tr>
<td>E78.01</td>
<td>Familial hypercholesterolemia</td>
</tr>
<tr>
<td>E78.1</td>
<td>Pure hyperglyceridemia</td>
</tr>
<tr>
<td>E78.2</td>
<td>Mixed hyperlipidemia</td>
</tr>
<tr>
<td>E78.3</td>
<td>Hyperchylomicronemia</td>
</tr>
<tr>
<td>E78.4</td>
<td>Other hyperlipidemia</td>
</tr>
<tr>
<td>E78.5</td>
<td>Hyperlipidemia, unspecified</td>
</tr>
</tbody>
</table>

**Diagnoses that Support Medical Necessity**

N/A

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

N/A

**Diagnoses that DO NOT Support Medical Necessity**

N/A

**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 policy, 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 policy 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 and Basis for Decision

FCSO reference LCD number – L29437


**Start Date of Comment Period**

N/A

**End Date of Comment Period**

N/A

**Start Date of Notice Period**

04/01/2014

**Revision History**

**Revision History Number: 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 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.

**Original**
Publication: April 2014 Connection

This LCD replaces all previous LCD versions (refer to “Sources of Information and Basis for Decision” section of the LCD) and publications on this subject to comply with ICD-10-CM based on Change Request 8112. The effective date of this LCD is based on date of service.

**Related Documents**

N/A

**LCD Attachments**

N/A