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

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>
<th>State(s)</th>
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**LCD Information**

**Document Information**

- **LCD ID**: L34856
  - **OriginalEffective 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

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C-Reactive Protein High Sensitivity Testing (hsCRP)

Proposed LCD in Comment Period
N/A

Source Proposed LCD
N/A

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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.
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.

- 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.

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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 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.

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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.
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:**

<table>
<thead>
<tr>
<th>ICD-10 Codes</th>
<th>Description</th>
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<tr>
<td>E78.00</td>
<td>Pure hypercholesterolemia, unspecified</td>
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<td>E78.01</td>
<td>Familial hypercholesterolemia</td>
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<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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<tr>
<td>E78.4</td>
<td>Other hyperlipidemia</td>
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<td>I25.10</td>
<td>Atherosclerotic heart disease of native coronary artery without angina pectoris</td>
</tr>
<tr>
<td>Z74.09*</td>
<td>Other reduced mobility</td>
</tr>
<tr>
<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-E78.4).*

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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### Revision History Information

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<tr>
<td>10/01/2016</td>
<td>R4</td>
<td>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.</td>
<td>• Revisions Due To ICD-10-CM Code Changes</td>
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<td>04/07/2016</td>
<td>R3</td>
<td>Added standard language to the Utilization Guidelines section.</td>
<td>• Other (Clarification )</td>
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<td>04/07/2016</td>
<td>R2</td>
<td>LCD posted for notice on 02/19/2016 to become effective 04/07/2016.</td>
<td>• Creation of Uniform LCDs With Other MAC Jurisdiction</td>
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<tr>
<td>10/01/2015</td>
<td>R1</td>
<td>09/17/2015 DL34856 Draft LCD posted for Comments.</td>
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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 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**

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