

High Sensitivity C-Reactive Protein (hsCRP)

CPT: 86141

CMS Policy for Florida, Puerto Rico, and U.S. Virgin Islands

Local policies are determined by the performing test location. This is determined by the state in which your performing laboratory resides and where your testing is commonly performed.

Medically Supportive
ICD Codes are listed
on subsequent page(s)
of this document.

Coverage Indications, Limitations, 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.

Indications

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

Visit [QuestDiagnostics.com/MLCP](https://www.questdiagnostics.com/MLCP) to view current limited coverage tests, reference guides, and policy information.

To view the complete policy and the full list of medically supportive codes, please refer to the CMS website reference

www.cms.gov

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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 policy.

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.

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There is a frequency associated with this test. Please refer to the Limitations or Utilization Guidelines section on previous page(s).

The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare's limited coverage policy. **If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.**

Code	Description
E78.00	Pure hypercholesterolemia, unspecified
E78.01	Familial hypercholesterolemia
E78.1	Pure hyperglyceridemia
E78.2	Mixed hyperlipidemia
E78.3	Hyperchylomicronemia
E78.4	Other hyperlipidemia
E78.5	Hyperlipidemia, unspecified

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Disclaimer:
This diagnosis code reference guide is provided as an aid to physicians and office staff in determining when an ABN (Advance Beneficiary Notice) is necessary. Diagnosis codes must be applicable to the patient's symptoms or conditions and must be consistent with documentation in the patient's medical record. Quest Diagnostics does not recommend any diagnosis codes and will only submit diagnosis information provided to us by the ordering physician or his/her designated staff. The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

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