UM-CDG-098 High Sensitivity C Reactive Protein	Approved By: Director, Health Services	Effective Date: 10/16/2025

This Policy applies to all SECUR affiliates, associates, and subsidiaries.

Approved by Courtney Gonzales, Director of Health Services on behalf of the Utilization Management Committee.

PURPOSE

This coverage determination guideline serves to address C-reactive protein (CRP), an inflammatory biomarker.

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 sex, 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.

For SECUR Health Plan members, National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) will be applied to requests when applicable. SECUR Health Plan Coverage Determination Guidelines (CDG) will be utilized in the absence of an appropriate NCD and/or LCD.

DEFINITIONS
None

POLICY
SECUR Health Plan considers high-sensitivity C-reactive protein (hsCRP) as medically necessary when all 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

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).

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.

References:

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