

Reimbursement Policy

Biomarkers for Myocardial Infarction and Chronic Heart Failure

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I. Policy Description

Cardiac biomarkers are the biochemical markers released in blood from injured myocardial tissue in both acute and chronic conditions, such as myocardial infarction or heart failure. They become elevated in blood after a certain period and can be measured. Examples of cardiac biomarkers commonly used in the acute clinical setting include troponin and creatine kinase MB isoenzyme (CKMB) (Thygesen et al., 2007). Others, such as suppression of tumorigenicity 2 (ST2), can serve in long-term as markers of cardiomyocyte stress and fibrosis for risk stratification of patients with a wide spectrum of cardiovascular diseases (Bayes-Genis et al., 2015).

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

- 1) For individuals presenting with signs and symptoms of acute coronary syndrome (see Note 1), **quantitative** measurement of cardiac troponin (troponin T or I) for the diagnosis of myocardial infarction (MI) (when tested at an outpatient facility capable of performing an adequate clinical MI evaluation) **MEETS COVERAGE CRITERIA** up to four times within the first 72 hours following initial presentation.
- 2) For individuals presenting with signs and symptoms of acute coronary syndrome (see Note 1), measurement of following cardiac biomarkers for the diagnosis and/or prognosis of MI **DOES NOT MEET COVERAGE CRITERIA**:
 - a) Aspartate aminotransferase (AST/SGOT).
 - b) Cardiac creatine kinase isoenzyme MB (CKMB).
 - c) Creatine kinase (CK).
 - d) Creatine kinase isoenzymes.
 - e) Lactate dehydrogenase (LD, LDH).
 - f) Myoglobin.

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- 3) Measurement of B-type natriuretic peptide (BNP) **or** N-terminal proBNP (NT-proBNP) **MEETS COVERAGE CRITERIA** in **any** of the following situations:
 - a) To diagnose heart failure in individuals presenting with dyspnea.
 - b) To establish disease severity in individuals with chronic heart failure (up to four times per year in the outpatient setting).
- 4) For individuals presenting with signs and symptoms of acute coronary syndrome (see Note 1), measurement of cardiac biomarkers in an outpatient setting which is not capable of performing adequate clinical MI evaluation (e.g., independent lab or physician's office) **DOES NOT MEET COVERAGE CRITERIA.**
- 5) In the outpatient setting, **qualitative** measurement of cardiac troponin (troponin T or I) **DOES NOT MEET COVERAGE CRITERIA.**

The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.

- 6) For individuals presenting with signs and symptoms of acute coronary syndrome (see Note 1), measurement of the following cardiac biomarkers for the diagnosis and/or prognosis of MI **DOES NOT MEET COVERAGE CRITERIA:**
 - a) Copeptin.
 - b) Troponin C.
 - c) C-reactive protein.
 - d) Heart-type fatty acid binding protein (H-FABP).
 - e) Any other cardiac biomarkers not listed above.
- 7) For all situations in the outpatient setting, analysis of ST2 and/or its isoforms (e.g., Presage ST2) **DOES NOT MEET COVERAGE CRITERIA.**

NOTES:

Note 1: *Acute Coronary Syndrome/Myocardial Infarction Common Signs and Symptoms (Reeder, 2024):*

- Ischemic chest pain with radiation to an upper extremity, radiation to both arms, and pain associated with diaphoresis or with nausea and vomiting.

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- Squeezing, tightness, pressure, constriction, crushing, strangling, burning, heartburn, fullness in the chest, band-like sensation, knot in the center of the chest, lump in throat, ache, heavy weight on chest and toothache (when there is radiation to the lower jaw).
- Ischemic pain often radiates to other parts of the body including the upper abdomen (epigastrium), shoulders, arms (upper and forearm), wrist, fingers, neck and throat, lower jaw and teeth (but not upper jaw), and not infrequently to the back (specifically the interscapular region).
- Shortness of breath, belching, nausea, indigestion, vomiting, diaphoresis, dizziness, lightheadedness, clamminess, and fatigue.

Atypical Signs and Symptoms (Reeder, 2024):

Dyspnea alone, weakness, nausea and/or vomiting, epigastric pain or discomfort, palpitations, syncope, or cardiac arrest.

III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: <https://www.cms.gov/medicare-coverage-database/search.aspx>. For the most up-to-date Medicaid policies and coverage, visit the applicable state Medicaid website.

Food and Drug Administration (FDA)

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
82550	Creatine kinase (CK), (CPK); total
82552	Creatine kinase (CK), (CPK); isoenzymes
82553	Creatine kinase (CK), (CPK); MB fraction only
82554	Creatine kinase (CK), (CPK); isoforms
82725	Fatty acids, nonesterified
83006	Growth stimulation expressed gene 2 (ST2, Interleukin 1 receptor like-1)
83615	Lactate dehydrogenase (LD), (LDH);

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83625	Lactate dehydrogenase (LD), (LDH); isoenzymes, separation and quantitation
83874	Myoglobin
83880	Natriuretic peptide
84450	Transferase; aspartate amino (AST) (SGOT)
84484	Troponin, quantitative
84512	Troponin, qualitative
84588	Vasopressin (antidiuretic hormone, ADH)
84999	Unlisted chemistry procedure
86140	C-reactive protein

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Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

V. Evidence-based Scientific References

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