

Clinical Policy: Cardiac Biomarker Testing

Reference Number: WNC.CP.145

Last Review Date:

Coding Implications
Revision Log

See <u>Important Reminder</u> at the end of this policy for important regulatory and legal information.

Note: When state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Description

The release of cardiac biomarkers is among the cascade of events that occur during acute coronary syndromes and cardiac ischemia. This policy discusses the medical necessity requirements for testing of these cardiac biomarkers.

Policy/Criteria

- It is the policy of WellCare of North Carolina[®] that troponin I or T testing is medically necessary and the appropriate cardiac biomarker for evaluating for suspected acute myocardial infarctions (AMI) or myocardial injury due to other mechanisms.
- II. It is the policy of WellCare of North Carolina® that creatine kinase myocardial isoenzyme (CK-MB) and myoglobin testing are **not medically necessary** in the evaluation for suspected AMI because troponin is the recommended biomarker due to its superior sensitivity and accuracy.

Background

Detection of specific cardiac biomarkers in blood serum is a useful clinical indication of AMI, myocarditis, or heart failure.² Cardiac troponins I and T have become the preferred biomarkers used for the diagnoses of acute coronary syndromes, due to their high specificity and sensitivity and because these subunits are expressed in the myocardium.¹⁻⁷ Furthermore, troponin levels are also elevated for acute and chronic decompensated heart failure in instances of myocyte injury and/or necrosis.⁷⁻⁸

Other cardiac peptides that were previously assessed for AMI include creatine kinase myocardial isoenzyme (CK-MB) and myoglobin. However, recent evidence suggests that the sensitivity and specificity of these biomarkers are inferior compared to the troponins, suggesting that troponins are a more accurate biomarker of myocardial injury. According to the 2014 American College of Cardiologists/American Heart Association (ACC/AHA) clinical practice guideline, CK-MB and myoglobin are no longer necessary for acute coronary syndrome diagnosis as a result of the advent of troponin assays. CK-MB detection is comparatively less sensitive and less specific. A 2010 retrospective cohort study was performed in an emergency department over a 12 month period examining patients who had troponin testing. The study included 11,092

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visits where at least one troponin test was ordered, and 97.9% of these patients also had a CK-MB ordered. The authors concluded that CK-MB can be omitted during the initial screening of AMIs since the study showed a 0% rate of positive CK-MB index with negative troponin. Eggers et al evaluated the role of myoglobin with troponin I to detect AMI in a sample of 197 patients and determined that neither myoglobin nor CK-MB added clinical diagnostic value. Of note, Singh et al measured CK-MB testing from 2007 to 2013 and found a dramatic decrease from 12,057 tests in 2007 to 36 tests in 2013.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2024, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| CPT®* | Description | | |
|---|---|--|--|
| Codes | | | |
| CPT codes not medically necessary when billed with CPT 84484 Troponin | | | |
| 82553 | Creatine kinase (CK), (CPK); MB fraction only | | |
| 83874 | Myoglobin | | |

| Reviews, Revisions, and Approvals | Reviewed Date | Approval Date |
|--|------------------|------------------|
| Original approval date | | 05/21 |
| Reviewed CPT codes. | | 02/22 |
| Annual Review. CPT codes reviewed. References updated. | | 11/22 |
| NCHC verbiage removed from NC Guidance Verbiage. | | 04/23 |
| Annual review. Background updated with no impact on criteria. | 08/23 | 08/23 |
| References reviewed and updated | | |
| Annual review. Policy named changed to "Cardiac Biomarker Testing | 11/23 | 11/23 |
| for Acute Myocardial Infarction" Background updated with no impact | | |
| on criteria. Coding reviewed. Removed HCPCSC and ICD-10-CM | | |
| tables. References reviewed and updated. | | |
| Annual Review. Removed "for acute myocardial infarction" from title. | | |
| References reviewed and updated. | | |

References

- 1. Jaffe AS, Morrow DA. Biomarkers of myocardial injury other than troponin. UpToDate. www.uptodate.com. Published February 15, 2021. Accessed August 10, 2023.
- 2. Amsterdam EA, Wenger NK, Brindis RG, et al. 2014 AHA/ACC guideline for the management of patients with non-ST-elevation acute coronary syndromes: a report of the

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American College of Cardiology/American Heart Association Task Force on Practice Guidelines [published correction appears in Circulation. 2014 Dec 23;130(25):e433 to 4. Dosage error in article text]. Circulation. 2014;130(25):e344 to e426. doi:10.1161/CIR.0000000000000134

- 3. Neumann JT, Sörensen NA, Schwemer T, et al. Diagnosis of Myocardial Infarction Using a High-Sensitivity Troponin I 1-Hour Algorithm. JAMA Cardiol 2016;1(4):397 to 404. doi:10.1001/jamacardio.2016.0695
- 4. Reeder GS, Kennedy HL. Diagnosis of acute myocardial infarction. UpToDate. www.uptodate.com. Published October 5, 2022. Accessed August 10, 2023.
- 5. deFilippi C, Henrich WL. Cardiac troponins in patients with kidney disease. UpToDate. www.uptodate.com. Published June 09, 2022. Accessed August 10, 2023.
- 6. Jaffe AS, Morrow DA. Troponin testing: Clinical use. UpToDate. www.uptodate.com. Published April 06, 2022. Accessed August 10, 2023.
- 7. Local coverage determination: Troponin (L33974). Centers for Medicare and Medicaid Services Web site. http://www.cms.hhs.gov/mcd/search.asp. Published October 01, 2015 (revised October 01, 2019). Accessed August 10, 2023.
- 8. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. Circulation. 2017;136(6):e137 to e161. doi:10.1161/CIR.000000000000000099
- 9. Volz KA, McGillicuddy DC, Horowitz GL, Sanchez LD. Creatine kinase-MB does not add additional benefit to a negative troponin in the evaluation of chest pain. Am J Emerg Med 2012;30(1):188 to 190. doi:10.1016/j.ajem.2010.10.016
- 10. Eggers KM, Oldgren J, Nordenskjöld A, Lindahl B. Diagnostic value of serial measurement of cardiac markers in patients with chest pain: limited value of adding myoglobin to troponin I for exclusion of myocardial infarction. Am Heart J. 2004;148(4):574 to 581. doi:10.1016/j.ahj.2004.04.030
- 11. Singh G, Baweja PS. Creatine kinase–MB: the journey to obsolescence. Am J Clin Pathol 2014;141(3):415 to 419. doi:10.1309/AJCPBIK3G4BWEJKO

North Carolina Guidance

Eligibility Requirements

- a. An eligible beneficiary shall be enrolled in the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise);
- b. Provider(s) shall verify each Medicaid beneficiary's eligibility each time a service is rendered.
- c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]
Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or

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procedures for Medicaid beneficiary under 21 years of age if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

- 1. that is unsafe, ineffective, or experimental or investigational.
- 2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

- 1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does NOT eliminate the requirement for prior approval.
- 2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below:

NCTracks Provider Claims and Billing Assistance Guide: https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html EPSDT provider page: https://medicaid.ncdhhs.gov/

Provider(s) Eligible to Bill for the Procedure, Product, or Service
To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

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- a. meet Medicaid qualifications for participation;
- b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:

- a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
- b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

Claims-Related Information

Provider(s) shall comply with the NC Tracks Provider Claims and Billing Assistance Guide, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid:

- a. Claim Type as applicable to the service provided:
 - Professional (CMS-1500/837P transaction)
 - Institutional (UB-04/837I transaction)
 - Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.
- b. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.
- c. Code(s) Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy. If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

Unlisted Procedure or Service

CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

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HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service

- d. Modifiers Providers shall follow applicable modifier guidelines.
- e. Billing Units Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
- f. Co-payments For Medicaid refer to Medicaid State Plan:
 https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan
- g. Reimbursement Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise



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professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

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