

**ANNUAL NOTICE TO PHYSICIANS 2019**

CaroMont Health Laboratory is providing this annual notice in accordance with recommendations made by the Office of Inspector General (OIG) of the Department of Health and Human Services, to provide physicians and non-physician providers with notice of, and education about laboratory compliance.

This notice highlights areas of regulatory focus and concern, and is intended to help both the physician client and the laboratory comply with these regulations and mitigate the risks for all parties.

Please review this summary of applicable Medicare regulations, billing rules, and compliance guidelines related to laboratory services. If you have questions about the content of this notice, we encourage you to contact us for more information.

**Licensed Physicians and Non-Physician Practitioners (NPP):**

A laboratory may only bill Medicare and Medicaid for testing ordered by a licensed physician or other individuals authorized to order laboratory tests. If your license has been revoked or suspended, please notify the laboratory immediately at 704-834-2881. Medicare requires individuals ordering laboratory services to be registered in the Centers for Medicare and Medicaid Services Provider Enrollment Chain and Ownership System (PECOS). Additional information on PECOS and how to enroll in the system may be viewed at: https://pecos.cms.hhs.gov/pecos/login.do#headingLv1

 **Medicare will only pay for medically necessary tests:**

The OIG has advised laboratories to remind physicians (or other individuals authorized by law to order tests) to ensure that when ordering tests for which Medicare reimbursement will be sought, they should only order tests that are medically necessary for the diagnosis or treatment of a patient. Section 1862(a)(1)(A) of the Medicare law states, “no payment may be made under Part A or Part B for any expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member”.

Accordingly, Medicare may deny payment for a test that you believe is appropriate, but which does not meet the Medicare coverage criteria (i.e. a test done for screening purposes or part of a routine physical examination does not meet the coverage criteria) or where documentation in the patient record (including the patient record you maintain) does not support a finding that the test was reasonable and necessary, for a given patient.

 **Diagnosis Code Selection & Documentation:**

Documentation in the patient’s medical record must support the medical necessity of the test(s) ordered. We ask that you provide CaroMont laboratory with all relevant diagnostic information requested with the electronic order or paper requisition. ICD-10 codes must be provided for each test and service ordered for billing and documentation purposes. When selecting an ICD-10 code, always select the code most specific to the patient’s condition and reason for the test.

**Ordering Panel or Profiles:**

Physicians and authorized providers should only order AMA defined Organ / Disease Panels when all components are medically necessary. In cases where only certain components are medically necessary, individual tests or a less inclusive panel should be ordered.

 **Screening, Preventive, Routine Testing:**

Medicare does NOT cover routine screening laboratory tests, with the exception of a few specifically cited exceptions. For specific coverage, frequency and diagnosis coding requirements for those covered screening tests, see the CMS Quick Reference Chart for Preventative Services at: <https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html>

**Medicare Coverage Policies for Laboratory Testing:**

Medicare has established both national and local medical review policies for specific laboratory tests. These policies include a list of diagnosis codes indicating what clinical circumstance justify the medical necessity of an individual test. In addition, these policies contain information including specific non-covered diagnosis codes, coding guidelines, reason for denial and frequency limitations.

**National Coverage Decisions (NCD):**

CMS has developed and published National Coverage Determination (NCD**)**. These guidelines give direction for medical necessity on selected laboratory tests.

View all laboratory NCDs at:

 <http://www.cms.gov/medicare-coverage-database/indexes/ncd-alphabetical-index.aspx>?

 **Local Coverage Determinations (LCD)**

 CMS has authorized Medicare Contractor Palmetto GBA to develop Local Coverage Determinations for NC & SC. These guidelines may supplement or be in addition to the National Coverage Determinations, and give direction for medical necessity on selected laboratory tests. Local Coverage Determinations may not contradict National Coverage Determinations.

 View NC & SC LCDs at : [https://www.cms.gov/medicare-coverage-database/indexes/lcd- list.aspx?Cntrctr=374&ContrVer=1&CntrctrSelected=374\*1&LCntrctr=374\*1%7c375\*1%7c376\*1%7c377\*1&DocType=2&bc=AgACAAAAAAAA&#aFinal](https://www.cms.gov/medicare-coverage-database/indexes/lcd-list.aspx?Cntrctr=374&ContrVer=1&CntrctrSelected=374*1&LCntrctr=374*1%7c375*1%7c376*1%7c377*1&DocType=2&bc=AgACAAAAAAAA&#aFinal)

 **Clinical Consultants:**

CaroMont Laboratory has clinical consultants available to answer questions regarding appropriate test selection and ordering. For a clinical consultation with a pathologist or technical manager, please contact Laboratory Customer Service at 704-834-2881.

**Penalties:**

As a Medicare participating provider, CaroMont Laboratory has a responsibility to make good faith efforts to ensure that all tests requested are performed and billed in a manner consistent with all federal and state laws and regulations. The OIG takes the position that physicians or other individuals authorized to order laboratory tests, who knowingly cause a false claims to be submitted to any federally funded program, may be subject to sanctions or remedies available under civil, criminal, and administrative law, such as the False Claim Act.

 **Advance Beneficiary Notices (ABN):**

 Medicare can deny reimbursement for tests based upon the absence of a diagnosis or ICD-10 code that supports medical necessity, investigational use only tests and frequency limitations. An ABN signed by the patient prior to service is necessary to document that the patient is aware that Medicare may not pay for a tests and that the patient has agreed to be responsible for payment in the event Medicare payment is denied. It is the responsibility of the physician or authorized party to obtain a properly completed ABN when the patient is serviced in his / her office. The completed ABN form should then accompany the patient or specimen to the laboratory.

 **Reflex Testing:**

For some laboratory tests, when certain criteria are met, additional testing will be generated to provide more conclusive information for diagnosis and treatment. The CPT code will accurately reflect the testing that is performed. If you determine that reflex testing is not medically necessary, you may indicate on the requisition by listing only the specific test or component needed, or by indicating “No Reflex” on the requisition, or contact the laboratory directly.

 **2019 Medicare Clinical Diagnostic Laboratory Tests Payment System:**

 Effective January 1, 2018, the Clinical Lab Fess Schedule (CLFS) reimbursement rates were revised to

 be based on the weighted median private payor rates as required by the Protecting Access to

 Medicare Act (PAMA) of 2014. Co-payments and deductibles do not apply to services paid under the

 Medicare clinical laboratory fee schedule. Also, Medicaid reimbursement will be equal to, or less

 than Medicare reimbursement. The 2019 Medicare Clinical Laboratory Fee schedule may be viewed

 and downloaded at:

[https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20Laboratory-Fee-Schedule-Files.html)

 [Laboratory-Fee-Schedule-Files.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20%20Laboratory-Fee-Schedule-Files.html)

 **Pre-Authorization for Lab Services:**

Insurance payors continue to increase oversight and restrict access by requiring pre-authorization for certain lab tests, including but not limited to Genetic Markers, Cytogenetics and Molecular testing. Please work with your patient to review their payor-specific preauthorization requirements. Any preauthorization paperwork must be completed by the ordering provider’s office prior to submission of any lab orders and / or specimens. Please include the preauthorization number on the order, along with any related documentation. If preauthorization is required by the payor but is not done by the ordering provider prior to submission, the laboratory may delay or suspend processing until the required authorization can be completed.

CaroMont Health Laboratory is committed to compliance with all federal, state and local laws, and to adhere to all program requirements for federal, state and private health plans. Your partnership with CaroMont Health Laboratory is fundamental to the success of our compliance program, and we thank you for your cooperation and continued participation.

If you have any questions or comments about this annual notice, any information contained, or any other issue or concern related to laboratory compliance, please contact David Mills, Laboratory Administrative Director at david.mills@caromonthealth.org or 704-834-2885.

Attachments: 2019 AMA Recognized Organ / Disease Panels



**Medical Necessity of Panels and Profiles**

It is the position of The Office of Inspector General (OIG), that the use of panels and profiles may result in medically unnecessary testing. When panels or profiles are ordered on Medicare beneficiaries, please ensure that all of the individual component tests are medically necessary. In cases where only certain components are medically necessary, individual tests or a less inclusive panel or profile should be ordered.

CaroMont Laboratory encourages the ordering of only medically necessary tests.

**2019 AMA Organ & Disease Panels**

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| **Panel & Components** | **Panel****CPT** | **2019 NC Medicare Allowable** |
| **Electrolyte Panel:** Sodium, Potassium, CO2, Chloride | 80051 | 7.79 |
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| **Basic Metabolic Panel:** Sodium, Potassium, Chloride, CO2, BUN, Creatinine, Glucose, Calcium | 80048 | 9.40 |
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| **Comprehensive Metabolic Panel:** Albumin, Total Bilirubin, Calcium, CO2, Chloride, BUN, Creatinine, Glucose, Alkaline Phosphatase, Potassium, Total Protein, Sodium, ALT, AST | 80053 | 11.74 |
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| **Hepatic Function Panel:** Albumin, Total & Direct Bilirubin, Alkaline Phosphatase, Total Protein, ALT, AST | 80076 | 9.08 |
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| **Acute Hepatitis Panel:**  Hepatitis A IgM Ab, Hepatitis B core IgM Ab, Hepatitis B surface Ag, Hepatitis C Ab | 80074 | 52.93 |
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| **Lipid Panel:** Cholesterol, Triglycerides, HDL Cholesterol, Calculated LDL & Coronary Risk Factor  | 80061 | 14.88 |
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| **Obstetric Panel:** Antibody Screen, Blood Typing ABO, Rh(D), CBC w/Differential, Hepatitis B Surface Antigen, RPR, Rubella Antibody | 80055 | 53.12 |
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| **Renal Function Panel:** Albumin, Calcium, CO2, Chloride, Creatinine, Glucose, Phosphorous, Potassium, Sodium, BUN | 80069 | 9.65 |

**Avoid Duplicate Ordering of Panels and Tests**

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| **Incorrect Order** | **Correct Order** |
| CMP and Renal Function Panel | CMP and Phosphorous |
| CMP and Hepatic Function Panel | CMP and Bilirubin, Direct |
| BMP and Renal Function Panel | Renal Function Panel |