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How Well Do You Know CMS' Medical Necessity Rules for Clinical Laboratory Tests?

On February 28, 2018, the U.S. Attorney's Office for the District of Vermont announced that Brattleboro Memorial Hospital (BMH) paid \$1,655,000 to settle allegations that it violated both the Federal False Claims Act and Vermont's False Claims Act in billing outpatient laboratory tests from approximately January 2012 through September 2014. Initiated by a qui tam whistleblower lawsuit, the suit contended that during that time period BMH knowingly submitted, or caused to be submitted, claims for outpatient lab testing that lacked the necessary documentation to support reimbursement by Medicare and Medicaid. In some cases, "the clinicians' orders for laboratory tests did not appear to adequately document the diagnosis code included on the billing claim form as required."

It is important to note that there were no allegations that the services billed for weren't provided or were unnecessary; only that they were not properly documented. BMH did not admit to any intentional wrongdoing and subsequently made the necessary systems and operational improvements to correct the problems that led to the improper billing.

We all know that Medicare normally covers services deemed medically necessary. But what many don't realize is that CMS has strict standards for demonstrating medical necessity for many services – including clinical lab testing. The Office of the Inspector General's (OIG) **Model Compliance Plan for Clinical Laboratories** provides specific guidance to labs for establishing best practices to reduce fraud, waste and abuse, and promoting alignment with industry healthcare laws. While implementing such a compliance plan is voluntary, complying with the regulations that the plan represents, is not.

The full text of the Model Compliance Plan for Clinical Laboratories resides at the following link:
<https://oig.hhs.gov/fraud/docs/complianceguidance/cpcl.html>

The Model Compliance Plan states that the OIG acknowledges that physicians must be able to order any tests, including screening tests, that they believe are appropriate for the treatment of their patients. However, according to the OIG, "...Medicare will only pay for tests that meet the Medicare definition of 'medical necessity' and... may deny payment for a test that the physician believes is appropriate, such as a screening test, but which does not meet the Medicare definition of medical necessity. The laboratories themselves are in a unique position to deliver this information to their physician clients."

Further, labs are advised to implement steps to help ensure that the tests they are requested to run and submit claims for meet program requirements. To do so, one of the Plan's recommended steps is to standardize the requisition form. The form should require ordering physicians to document the need for each test by inserting a diagnosis code for each test. Labs are advised to contact ordering physicians to obtain diagnostic information in the event they have failed to provide it.

What constitutes medical necessity for clinical lab tests?

Medicare has designated lists of tests that must be accompanied by specific diagnostic information to establish medical necessity before Medicare coverage will be assumed. As such, the Plan advises that, "Laboratory compliance policies should direct that laboratories will only submit diagnostic information obtained from the test-ordering physician."



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Where are these lists located?

At the individual Medicare MAC level, CMS' Local Coverage Determinations (LCD) are examples of local policies containing diagnosis requirements and other criteria needed to establish medical necessity for designated services and tests. At the national level, **Medicare's National Coverage Determinations (NCD) Coding Policy Manual for Clinical Diagnostic Laboratory Services** is a comprehensive listing of the NCD's and their individual diagnosis requirements exclusively for clinical laboratory tests.

<https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/LabNCDsICD10.html>

A summary of the current list of NCDs for clinical laboratory testing follows.

NCD #	Description	NCD #	Description
190.12	Urine Culture, Bacterial	190.13	HIV Testing, Prognosis incl. Monitoring
190.14	HIV Testing, Diagnosis	190.15	Blood Counts
190.16	Partial Thromboplastin Time (PTT)	190.17	Prothrombin Time (PT)
190.18	Serum Iron Studies	190.19	Collagen Crosslinks, any method
190.20	Blood Glucose Testing	190.21	Glycated Hemoglobin/Glycated Protein
190.22	Thyroid Testing	190.23	Lipids Testing
190.24	Digoxin Therapeutic Drug Assay	190.25	Alpha-fetoprotein
190.26	Carcinoembryonic Antigen	190.27	Human Chorionic Gonadotropin
190.28	Tumor Antigen by Immunoassay CA125	190.29	Tumor Antigen by Immunoassay CA 15-3/CA 27.29
190.30	Tumor Antigen by Immunoassay CA 19-9	190.31	Prostate Specific Antigen
190.32	Gamma Glutamyl Transferase		

The NCD policy manual is updated quarterly and contains additional valuable information for clinical laboratory services including:

- Indications and limitations
- Coding Guidelines
- ICD-10-CM codes that do not support medical necessity
- Documentation requirements
- Reasons for Denial

Armed with this collective information, it is easier to create and maintain lab policies and procedures that not only align with the laws and regulations governing clinical laboratory services, but serve to comply with the ordering and billing requirements of these services as well. This is critical for labs as there is ongoing monitoring by CMS through its Comprehensive Error Rate Testing (CERT) audit process.

What is a CERT Audit?

CERT audits are performed by CMS each year to calculate the Medicare Fee-for-Service (FFS) improper payment rate for payments made to Part A and B providers, durable medical equipment and the hospital Inpatient Prospective Payment System (IPPS). Through this process CERT analyzes a



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“statistically valid stratified random sample of claims” to determine if they were paid properly under Medicare coverage, coding and billing rules. To give an idea of the scope of these audits, the CERT improper payment rate for the 2017 fiscal year of the Medicare FFS program was determined to be 9.51%, equating to over \$36 billion.

How do CERT Audits apply to clinical laboratory testing services?

February 2018’s CMS/CGS Administrators’ webinar, **Ordering Lab Services** stated the majority of its lab testing-related CERT audits fail because of insufficient documentation and lack of medical necessity (i.e., missing an order, patient’s medical record doesn’t support the intent to order, lack of documented medical necessity for the test, etc.). Key highlights detail the documentation expectations for clinical lab services:

- Entities that bill for lab tests are required to obtain the physician’s signed order (or progress notes supporting intent to order) and documentation that supports medical necessity for the ordered service
 - ✓ Tip: This ties-back to the OIG’s Model Compliance Plan for Clinical Laboratories that advises labs to standardize their requisition forms to require a diagnosis code for each test ordered
- According to the webinar, if the provided diagnosis isn’t covered and the ordering provider is contacted for an updated code, a new order should be provided that supports the updated code and the medical record should be updated accordingly
- CERT auditors will look for the documentation to match between the patient’s medical record, the requisition, and the claim. In the event of a CERT audit, billing entities will need to obtain and submit patient medical records if the requisition doesn’t contain the required documentation

The complete recorded webinar can be accessed at the link below:

<https://register.gotowebinar.com/recording/8649228344589327618>

For additional information, click on the following link to review CMS’ Medicare Learning Network fact sheet, **Complying with Documentation Requirements for Laboratory Services**:

<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ProviderComplianceLabServices-Fact-Sheet-ICN909221.pdf>