



Manual: Laboratory Guide

Category: Provision of Care

Subject **Medical Necessity Requirements for Ordering Outpatient Laboratory Testing**

**Purpose:** Comply with government regulation, i.e., The Centers for Medicare and Medicaid Services (CMS) has mandated that medical necessity is documented for Medicare outpatients. Documentation in the patient's medical record must support the diagnosis information sent on the claim for reimbursement. An Advance Beneficiary Notice of Noncoverage (ABN) must be discussed with the patient when there is reason to believe that Medicare is likely to deny payment.

**Policy:** In order to assure that testing will be reimbursed:

- ◆ Order only tests that are medically necessary for diagnosis and treatment of the patient.
- ◆ Provide the diagnosis or reason for ordering the specific laboratory test(s). A narrative documentation of the diagnosis or the specific ICD-9 is acceptable. If narrative documentation is provided, the coding staff will assign the proper ICD-9 code(s).
- ◆ Ask patients to sign an ABN if the claim for testing is *likely* to be denied.

**Procedure: Introduction**

CMS administers the Medicare program. In order to ensure services paid by Medicare are medically necessary, CMS has directed its carriers and intermediaries to identify laboratory tests that require additional medical necessity documentation. Effective November 2002, there are 23 national policies, called National Coverage Decisions (NCD), that define the medical necessity documentation needed. In addition most carriers and intermediaries have established additional Local Coverage Decisions (LCD). The NCD and LCD define the documentation of medical necessity required before a claim will be paid. The LCD policies are developed by the Carrier Advisory Committee for each state, which includes physician representation. Medical necessity as defined by CMS lists the ICD-9 diagnosis codes, which justify payment for a specific laboratory test. For tests with an NCD or LCD, if the test is submitted for payment and does not have a corresponding ICD-9 code listed in the LCD, the claim will be denied.

In the event of a post payment review, the ICD-9 codes used on a claim must be consistent with documentation in the patient's medical record. The ICD-9 codes used must be specific to a particular patient and the laboratory tests ordered on the patient's behalf. In order to prevent denial for Medicare claims, the laboratory and billing department need the cooperation of the physician or other health care provider. Whenever laboratory testing is ordered, the reason for ordering the test must be provided with the order. If multiple tests are ordered on the same visit, the reasons for each test or panel must be provided. If no narrative diagnosis/reason or ICD-9 code is provided the laboratory will be required to call and obtain this information.

**Documentation Requirements**

- Documentation supporting medical necessity, such as ICD-9 diagnosis codes or comparable narrative must be submitted on all claims. Failure to do so may result in rejection or denial of claim(s).
- The ordering physician is required to retain in the patient's medical record, history and physical, examination notes documenting evaluation and management of one of the Medicare covered conditions/diagnoses, with relevant clinical signs/symptoms or abnormal laboratory test results, appropriate to one of the covered indications.
- There must be an attending/treating physician's order for each test documented in the patient's medical/clinical record. Medical records must clearly document the reason for the test, results, frequency, and an appropriate history and physical examination.
- Documentation in the medical record must be submitted to Medicare upon request or upon reconsideration of a claim.

**Advance Beneficiary Notice**

If Medicare denies reimbursement for medical necessity reasons, Medicare rules prohibit the laboratory or health care provider from billing the patient unless an Advance Beneficiary Notice of **Noncoverage** (ABN) has been signed by the patient prior to the service. Without a signed ABN, the provider cannot bill the patient for

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any denied services. Medicare rules prohibit the provider from ignoring this process and absorbing the cost of denied testing. The ABN includes the following information:

- Identifies patient date of service, laboratory test(s) to be performed, and reason the test(s) is likely to be denied.
- Assures that the patient understands he or she may be responsible for payment if the test is not considered to be medically necessary by Medicare.
- Allows the patient to make an informed decision whether or not to receive the service and pay for it out-of-pocket.

When the physician believes that a test ordered may not be covered, the physician should ensure the patient is informed of this possibility and that the ABN is signed. The most common reasons for claim denial for laboratory tests are:

- Tests are ordered for screening purposes. Medicare regards screening tests as non-covered services under section 1862 of Title XVIII of the Social Security Act. Although an ABN is not required for screening tests, it can be a helpful communication tool to make the patient aware that the ordered testing will not be covered.
- Medical necessity is not consistent with the LCD, i.e., the ICD-9 code provided is not on the covered list in the LCD.
- Test frequency limitation is exceeded, e.g., (a) Medicare will only reimburse for 4 glycosylated hemoglobin tests per year, or one every 13 weeks, (b) a screening PSA is covered once annually for males over 50 years of age, (c) a pap smear is covered once every two years on females.
- Medicare considers the test to be experimental and for research or investigational use only, e.g., newly introduced tumor markers.

CMS has built some specific steps into the ABN process which are important to remember:

- The ABN must be signed by the patient *before* the laboratory specimen is collected or *before* the test is performed.
- It is not necessary to have a Medicare patient sign an ABN for every test ordered. CMS has stated that an ABN should be discussed with the patient only when there is reason to believe that Medicare is likely to deny payment for service(s). CMS prohibits a practice called “blanket waiving” for all Medicare patients. Although it might be easier to have every Medicare patient sign a waiver, the process is intended to be an informed process based on the likelihood that the specific tests being ordered may be denied.
- If the patient chooses not to sign the ABN, the laboratory **will** decline to perform the test.

- Ext Ref:
- Updates in Clinical Laboratory Services-Ordering and Reimbursement, American Clinical Laboratory Association, 1997.
  - Noridian Medicare web site:  
[http://www.cms.hhs.gov/mcd/results\\_index.asp?from2=results\\_index.asp&contractor=83&from='lmprpcontractor'&retired=&name=Noridian%20Administrative%20Services,%20LLC%20\(00320,%20FI\)&letter\\_range=4&](http://www.cms.hhs.gov/mcd/results_index.asp?from2=results_index.asp&contractor=83&from='lmprpcontractor'&retired=&name=Noridian%20Administrative%20Services,%20LLC%20(00320,%20FI)&letter_range=4&)
  - Wisconsin Physician Services web site: [http://www.wpsmedicare.com/part\\_b/policy/policy\\_active.shtml](http://www.wpsmedicare.com/part_b/policy/policy_active.shtml)
  - Medicare National Coverage Determinations (NCD) Release Manual, July 2008, Centers for Medicare and Medicaid Services.

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