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. Most carriers have established this list of tests in the form of local medical review policies (LMRP). The LMRPs define the documentation of medical necessity required before a claim will be paid. The policies are developed by the Carrier Advisory Committee for each state, which includes physician representation. Some more commonly ordered tests will be covered by standardized national policies, known as National Coverage Decision (NCD), beginning in November 2002. There will continue to be local policies for other tests not covered by a national policy.

Medical necessity as defined by CMS lists the ICD-9 diagnosis codes which justify payment for a specific laboratory test. For tests with an LMRP, if the test is submitted for payment and does not have a corresponding ICD-9 code listed in the LMRP, 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 a signed 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 (ABN) or Patient Acknowledgment of Non-covered Services has been signed by the patient prior to the service. Without a signed ABN, the provider cannot bill the patient for 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.
- Medical necessity is not consistent with the LMRP, i.e., the ICD-9 code provided is not on the list in the LMRP.
- Test frequency limitation is exceeded, e.g., Medicare will only reimburse for 4 glycated hemoglobin tests per year, or one every 13 weeks.
- 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 waivering" 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 may decline to perform the test.

COMPLIANCE

In order to assure that testing will be reimbursed:

- Only order tests that are medically necessary (as defined by CMS) for the diagnosis and treatment of your patients.
- Provide the diagnosis or reason for ordering the specific laboratory tests. A narrative documentation of the diagnosis or the specific ICD-9 code will be acceptable. If non-coded documentation is provided, the coding staff will assign the proper ICD-9 code(s).
- Have patients sign an ABN if you believe that the claim for testing is *likely* to be denied.

References:

Updates in Clinical Laboratory Services-Ordering and Reimbursement, American Clinical Laboratory Association, 1997
Medicare Policy Manual, United Health Care, September 2000