



Introduction

Background

Section 4554(b)(1) of the Balanced Budget Act of 1997 (BBA), Public Law 105-33, mandated the use of a negotiated rulemaking committee to develop national coverage and administrative policies for clinical diagnostic laboratory services payable under Medicare Part B by January 1, 1999. This provision requires that these national coverage policies be designed to promote program integrity and national uniformity and simplify administrative requirements with respect to clinical diagnostic laboratory services in connection with the following:

- Beneficiary information required to be submitted with each claim or order for laboratory services;
- The medical condition(s) for which a laboratory test service is reasonable and necessary (within the meaning of section 1862(a)(1)(A) of the Social Security Act);
- The appropriate use of procedure codes in billing for a laboratory test service, including the unbundling of laboratory services;
- The medical documentation that is required by a Medicare contractor at the time a claim is submitted for a laboratory test service (in accordance with section 1833(e) of the Act);
- Record keeping requirements in addition to any information required to be submitted with a claim, including physicians' obligations regarding these requirements;
- Procedures for filing claims and for providing remittances by electronic media; and
- Limitations on frequency of coverage for the same services performed on the same individual.

On March 10, 2000, a proposed rule was published in the Federal Register (65 FR 13082) which set forth uniform national coverage and administrative policies for clinical diagnostic laboratory services. These proposed policies reflected the consensus of the Negotiated Rulemaking Committee. The final rule, published in the Federal Register on November 23, 2001 (66 FR 58788), addressed the public comments received on the proposed rule. The final rule established the national coverage and administrative policies for clinical diagnostic laboratory services payable under Medicare Part B. It promoted Medicare program integrity and national uniformity, and simplified administrative requirements for clinical diagnostic services. The 23 Lab NCDs for diagnostic lab test services, which are included in the 2001 Final Rule, are listed below.

- Culture, Bacterial, Urine
- Human Immunodeficiency Virus Testing (Prognosis including monitoring)
- Human Immunodeficiency Virus Testing (Diagnosis)
- Blood Counts
- Partial Thromboplastin Time
- Prothrombin Time
- Serum Iron Studies
- Collagen Crosslinks, Any Method



- Blood Glucose Testing
- Glycated Hemoglobin/Glycated Protein
- Thyroid Testing
- Lipids
- Digoxin Therapeutic Drug Assay
- Alpha-fetoprotein
- Carcinoembryonic Antigen
- Human Chorionic Gonadotropin
- Tumor Antigen by Immunoassay CA 125
- Tumor Antigen by Immunoassay CA 15-3/CA 27.29
- Tumor Antigen by Immunoassay CA 19-9
- Prostate Specific Antigen
- Gamma Glutamyl Transferase
- Hepatitis Panel/Acute Hepatitis Panel
- Fecal Occult Blood

What Is a National Coverage Policy?

Part B of title XVIII of the Social Security Act (the Act) provides for Supplementary Medical Insurance (SMI) for certain Medicare beneficiaries, specifying what health care items or services will be covered by the Medicare Part B program. The 23 diagnostic laboratory services described in this Manual are covered under Part B.

Services that are excluded from coverage include routine physical examinations and other services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury. CMS interprets these provisions to prohibit coverage of ‘screening’ services, including laboratory test services furnished in the absence of signs, symptoms, or personal history of disease or injury, except as explicitly authorized by statute. A test service might be considered medically appropriate, but nonetheless might be excluded from Medicare coverage by statute.

A national coverage policy for diagnostic laboratory test(s) is a document stating CMS’s policy with respect to the clinical circumstances in which the test(s) will be considered reasonable and necessary, and not screening, for Medicare purposes. Such a policy applies nationwide. A national coverage policy is neither a practice parameter nor a statement of the accepted standard of medical practice. Words such as “may be indicated” or “may be considered medically necessary” are used for this reason. Where a policy gives a general description and then lists examples (following words like “for example” or “including”), the list of examples is not meant to be all-inclusive but to provide some guidance.

What Is the Effect of a National Coverage Policy?

A national coverage policy to which this introduction applies is a National Coverage Decision (NCD) under section 1862(a) (1) of the Social Security Act. Regulations on National Coverage Decisions are codified at 42 CFR 405.732(b)–(d). A Medicare contractor may not develop a local policy that conflicts with a national coverage policy.



What Is the Format for These National Coverage Policies?

Below are the headings for national coverage policies, developed by the Negotiated Rulemaking Committee on Clinical Diagnostic Laboratory Tests.

Other Names/Abbreviations

This section identifies other names for the policy. It reflects more colloquial terminology.

Description

This section includes a description of the test(s) addressed by the policy and provides a general description of the appropriate uses of the test(s).

HCPCS Codes

The descriptor(s) used in this section is (are) the Current Procedural Terminology (CPT) or other CMS Common Procedure Coding System (HCPCS). The CPT© is developed and copyrighted by the American Medical Association (AMA). If a descriptor does not accurately or fully describe the test, a more complete description may be included elsewhere in the policy, such as in the 'Indications' section.

ICD-10-CM Codes Covered by Medicare Program

This section includes 'covered' codes – that is, codes for those lab test services for which Medicare provides the presumption of medical necessity, but may review a claim for such services to determine whether the service was in fact reasonable and necessary. The 'covered' diagnosis codes are from the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM). Where the policy takes an "exclusionary" approach, as described below, this section states: "Any ICD-10-CM code not listed in either of the ICD-10-CM code sections below."

Indications

This section lists detailed clinical indications for Medicare coverage of the test(s).

Limitations

This section lists any national frequency expectations, as well as other limitations on Medicare coverage of the specific test service addressed in the policy—for example, if it would be unnecessary to perform a particular test with a particular combination of diagnoses. In addition, coding guidelines specific to the diagnostic test service addressed in the policy might be included in this section.

ICD-10-CM Codes That Do Not Support Medical Necessity

This section lists/describes generally non-covered codes for which there are only limited exceptions. However, additional documentation could support a determination of medical necessity in certain circumstances. Subject to section 1879 of the Social Security Act (the Act), 42 CFR 411, subpart K, section 7330 of the Medicare Carriers Manual section 3440-3446.9 of the Medicare Fiscal Intermediary Manual and any applicable rulings, it would be appropriate for the ordering physician or the laboratory to obtain an advance beneficiary notice from the



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beneficiary. Where the policy takes an “inclusionary” approach, as described below, this section states: “Any ICD–10–CM code not listed in either of the ICD–10–CM sections above.”

Other Comments

This section may contain other relevant comments that are not addressed in the sections above, as well as coding guidance.

Documentation Requirements

This section refers to documentation requirements for clinical diagnostic laboratory tests at 42 CFR 410.32(d) and includes any specific documentation requirements related to the test(s) addressed in the policy.

Sources of Information

Relevant sources of information used in developing a Lab NCD are listed in this section.

Note: Additional general information about ICD-10-CM codes used in Medicare can be found on the CMS website, www.cms.gov/ICD10.