
CMS Manual System

Pub. 100-04 Medicare Claims Processing

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 234

Date: JULY 23, 2004

CHANGE REQUEST 3374

I. SUMMARY OF CHANGES: This one-time notification provides standardized language that may be used by contractors to respond to inquiries related to the negotiated national coverage determinations for clinical diagnostic laboratory services. Use of the language is optional for contractors.

NEW/REVISED MATERIAL - EFFECTIVE DATE: October 1, 2004

***IMPLEMENTATION DATE: October 4, 2004**

Disclaimer for manual changes only: The revision date and transmittal number apply only to the red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will only receive the new/revised information, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N/A	

***III. FUNDING:**

These instructions shall be implemented within your current operating budget.

IV. ATTACHMENTS:

	Business Requirements
	Manual Instruction
	Confidential Requirements
X	One-Time Notification
	Recurring Update Notification

***Medicare contractors only**

Attachment - One-Time Notification

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SUBJECT: Standardized Responses to Provider Inquiries Regarding the Negotiated Laboratory National Coverage Determinations (NCDs) Edit Software

I. GENERAL INFORMATION

A. Background: The NCDs for clinical diagnostic laboratory services were developed by the laboratory negotiated rulemaking committee and published as a final rule on November 23, 2001. Nationally uniform software has been developed by Computer Sciences Corporation (CSC) and incorporated in the shared systems so that laboratory claims subject to one of the 23 laboratory NCDs are processed uniformly throughout the nation. In an effort to further standardize the action of Medicare contractors regarding claims subject to one of the NCDs, CSC has developed language that can be used to respond to inquiries related to the NCDs and the edit module used to implement them.

B. Policy: This CR provides language (attached) that can be used to respond to commonly asked questions regarding the negotiated laboratory NCDs and the edit module used to implement the NCDs uniformly. Carriers and fiscal intermediaries may elect to use this language in responding to inquiries in their organization in order to help further standardized action nationally related to clinical diagnostic laboratory services.

C. Provider Education: None.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement

"Should" denotes an optional requirement

Requirement #	Requirements	Responsibility
3374.1	Carriers and FIs should use the attached language to respond to inquiries related to the negotiated lab NCDs and the edit module used to implement them.	Carriers and FIs

III. SUPPORTING INFORMATION & POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

<p>Effective Date: October 1, 2004</p> <p>Implementation Date: October 4, 2004</p> <p>Pre-Implementation Contact(s): Jackie Sheridan-Moore (410) 786-4635</p> <p>Post-Implementation Contact(s): Jackie Sheridan-Moore (410) 786-4635</p>	<p>These instructions shall be implemented within your current operating budget.</p>
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Attachment

Standardized Language for Negotiated National Coverage Determinations (NCDs) for Clinical Diagnostic Laboratory Services

1. What is a National Coverage Determination (NCD)?

CMS makes NCDs granting, limiting, or excluding Medicare coverage for a specific medical service, procedure, or device. NCDs are made under section 1862(a) (1) of the Social Security Act (the Act) or other applicable provisions of the Act. The national coverage decisions apply nationwide and are binding on all Medicare carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans for purposes of Medicare coverage.

2. What is a Clinical Laboratory Edit Table and what is its purpose?

The Clinical Laboratory NCD Edit Table is a diagnosis-to-procedure code edit table that is used by all Medicare contractors to process Medicare claims. The purpose of the edit table is to ensure that the Medicare claims subject to one of the negotiated laboratory NCDs are processed uniformly throughout the nation.

3. When did the Clinical Laboratory edit table become effective?

The Clinical Laboratory Edit Table became effective January 1, 2003. The negotiated laboratory NCDs became effective on November 25, 2002.

4. How often and why is the Clinical Laboratory NCD Edit Table updated?

The Clinical Laboratory NCD Edit Table is updated quarterly as necessary to reflect coding updates, ministerial coding changes, and substantive changes to the NCDs developed through the NCD process. Updates to the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology (CPT) are incorporated into the edit module so as not to substantively change the NCDs. Codes that flow from the narrative indications of the NCDs, but that were not initially included, may be added through coding analyses that are published on the coverage Internet site for public comment. Substantive policy changes resulting from new or modified NCDs for clinical laboratory services may also be developed and incorporated in the edit module quarterly updates.

5. Why were the negotiated laboratory NCDs initiated?

The negotiated laboratory NCDs were initiated to promote program integrity and national uniformity and to simplify administrative requirements for clinical diagnostic services.

6. Where can I find the list of Clinical Laboratory NCD procedure codes and coverage documentation?

There is a complete list of procedure codes and coverage information available on CMS website. The link to access the NCD Coding Policy Manuals, Federal Register Final Rules, and related CMS Program Memoranda is as follows: www.cms.hhs.gov/ncd/labindexlist.asp

7. How should a laboratory bill for services that are non-covered for reasons other than medical necessity?

Healthcare Common Procedure Coding System (HCPCS) coding provides for a GY modifier to be used to indicate an item or service that is statutorily excluded or does not meet the definition of any Medicare benefit. The list of non-covered codes for laboratory procedures subject to the negotiated NCDs can be found in the coding manuals in the “Non-covered ICD-9-CM Codes for All NCD Edits” section. These are the only codes that should be billed with the GY modifier for services subject to the negotiated laboratory NCDs. <http://www.cms.hhs.gov/ncd/labindexlist.asp>

8. Is there a procedure to follow if I disagree with the coverage policy of any of the negotiated laboratory NCDs?

If you are requesting a substantive change in an NCD, you must follow the NCD process that requires scientific evidence. Information regarding the NCD process is available on the Internet at www.cms.hhs.gov/coverage and clicking on the coverage process link.

CMS has developed a streamlined process for making coding changes that flow from the narrative indication of the negotiated lab NCDs. This was announced in the Federal Register (FR) on December 24, 2003 (68 FR 74607). Under this process, a coding analysis may be performed after a 30-day public comment period to determine if codes are appropriately listed in the NCD code lists.

Coding analyses do not require scientific evidence, as the substance of the NCD is not altered. In order to request a coding analysis, you must submit a request identifying the provision in the NCD narrative you believe supports the code. Send the request to the Coverage and Analysis Group, CMS, C1-09-06, 7500 Security Boulevard, Baltimore, Maryland 21244-1850

9. What diagnosis codes are used for the negotiated laboratory NCDs?

Every ICD-9-CM code falls into one of the 3 possible lists used in the edit module for the negotiated laboratory NCDs. The three code lists include: ICD-9-CM Codes Covered by Medicare, ICD-9-CM Codes Not Covered by Medicare, and ICD-9-CM Codes That Do Not Support Medical Necessity.

10. What causes an invalid code?

A code is invalid if it has not been coded to the full number of digits required for that code (Coding Clinic 1995 4th Quarter). Any series of numbers that is not linked to a description in the ICD-9-CM book is an invalid code.

11. How is probable, suspected, questionable, rule-out or working diagnosis coded?

Diagnoses documented as probably, suspected, questionable, rule-out, or working should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, and abnormal test results, exposure to communicable disease or other reasons for the visit.

12. How can I bill for a preoperative test for patients about to undergo surgery now that the NCD have removed the V72 series of ICD-9-CM codes?

Testing prior to any medical intervention associated with a risk of bleeding and thrombosis (other than thrombolytic therapy) will generally be considered medically necessary only where there are signs or symptoms of a bleeding or thrombotic abnormality or a personal history of bleeding, thrombosis or a condition associated with a coagulopathy. Hospital/clinic-specific policies, protocols, etc., in and of themselves, cannot alone justify coverage.

Assign the ICD-9-CM codes describing the signs, symptoms or conditions that justify the need for the test. If the signs, symptoms or conditions are not on the ICD-9-CM Codes Covered by Medicare list, they can still be submitted with the appropriate medical necessity documentation to substantiate the test. If no underlying signs, symptoms or conditions are present, a screening code must be used. In this instance, Medicare does not cover the screening coded test and payment will be the responsibility of the beneficiary.

13. I can't find the list of covered diagnoses for blood counts. Where is it?

The blood counts policy lists the ICD-9-CM Codes Not Covered by Medicare and the ICD-9-CM Codes That Do Not Support Medical Necessity. The list of ICD-9-CM Codes Covered by Medicare for blood counts is any diagnosis code not listed in either non-covered or not medically necessary lists.

14. I'm concerned my claims for sensitivity testing for specimens other than urine will deny as the covered list for codes 87184 and 87186 include only diagnosis that support urine culture sensitivities.

Claims for sensitivity testing on specimens other than urine will not deny as not medically necessary if they do not have a diagnosis from the ICD-9-CM Codes Covered by Medicare list of covered diagnoses for urine cultures. The edit module does not edit for these CPT codes. Rather, the NCD is intended to educate providers as to the appropriate indications to perform a urine culture sensitivity test.

15. Why doesn't Medicare cover a Prostate Specific Antigen (PSA) test for my patients with benign prostatic hypertrophy (BPH)?

The code for BPH, 600.00, is not on the ICD-9-CM Codes Covered by Medicare listing for a diagnostic PSA. Medicare does, however, cover an annual screening PSA testing for men over 50. Men with BPH receiving an annual PSA screening should have their claims coded with procedure code G0103 in lieu of CPT code 84153. This screening procedure code requires a diagnosis code of V76.44 that must appear on the claim form. If the patient has symptoms of prostate carcinoma along with the BPH, such as hematuria, nocturia, urinary frequency, and slow stream, a diagnostic PSA can be covered. More detailed information can be found in Program Memorandum AB-03-132:

http://www.cms.hhs.gov/manuals/pm_trans/AB03132.pdf

16. My contractor retired a Local Coverage Determination (LCD) related to one of the NCDs. Can I still get payment for the diagnoses covered in the LCD?

NCDs are binding on all Medicare claims processing contractors. Carriers and Fiscal Intermediaries may not have local policies that conflict with an NCD. Since the NCDs for the lab tests that were negotiated are specific to the code level, it is not possible for a local policy to deviate from the ICD-9-CM Codes Covered by Medicare list of diagnoses without being in conflict. However, contractors are authorized to pay for diagnoses on the ICD-9-CM Codes That Do Not Support Medical Necessity list if the laboratory submits satisfactory documentation along with the claim. In addition, contractors may develop local policies in areas where the NCD is silent.