

---

# CMS Manual System

## Pub. 100-04 Medicare Claims Processing

---

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

Transmittal 71

Date: JANUARY 23, 2004

---

### CHANGE REQUESTS 3032 and 3072

**I. SUMMARY OF CHANGES:** To provide clarification in the manual that the Medicare contractors will be receiving subsequently quarterly updates of the edit module to implement the national coverage determinations (NCDs) that were negotiated for clinical diagnostic laboratory services.

This instruction also communicates requirements to shared system maintainers and contractors notifying them of changes to the laboratory edit module to update it for changes in the NCDs for April 5, 2004.

**CLARIFICATION – EFFECTIVE DATE: January 23, 2004**

**IMPLEMENTATION DATE: April 5, 2004**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged.*

### II. CHANGES IN MANUAL INSTRUCTIONS:

(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N	16/120.2/Implementation and Updates of Negotiated National Coverage Determinations (NCDs) for Clinical Diagnostic Laboratory Services

### \*III. FUNDING:

These instructions shall be implemented within your current operating budget.

### IV. ATTACHMENTS:

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

\*Medicare contractors only

## Attachment - Business Requirements

Pub. 100-04	Transmittal: 71	Date: January 23, 2004	Change Request 3032
-------------	-----------------	------------------------	---------------------

**SUBJECT: Changes to the Laboratory National Coverage Determination (NCD) Edit Software**

### I. GENERAL INFORMATION

**A. Background:** The national coverage determinations (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 Science Corporation (CSC) and incorporated in the shared systems so that laboratory claims subject to one of the 23 NCDs are processed uniformly throughout the nation effective January 1, 2003.

**B. Policy:** The laboratory edit module for the NCDs will be updated quarterly as necessary to reflect ministerial coding updates and substantive changes to the NCDs developed through the NCD process.

**C. Provider Education:** None. However, intermediaries and carriers shall inform affected providers of the specific recurring changes to the NCDs as they are published by posting a summary on their Web site within 2 weeks of publication. Also, intermediaries and carriers shall publish the information on the specific updates in their next regularly scheduled bulletin. If they have a listserv that targets affected providers, they shall use it to notify subscribers that information about NCDs for clinical diagnostic laboratory services is available on their Web site.

### II. BUSINESS REQUIREMENTS

*"Shall"* denotes a mandatory requirement

*"Should"* denotes an optional requirement

Requirement #	Requirements	Responsibility
3032.1	The laboratory edit module developer contractor shall modify the edit software as directed by CMS and discussed in a recurring update notification.	CSC
3032.2	CSC shall make the revised software available to down load from the CMS data center via connect:direct. CSC shall notify the shared system maintainers of the data set names via E-mail.	CSC

3032.3	The shared system maintainers shall install the revised edit module after testing and distribute it to the carriers and intermediaries as part of their routine release.	ALL SSMs
3032.4	Carriers and intermediaries shall conduct provider education as directed above to advise laboratories of changes to the laboratory edit module.	All carriers and FIs

### III. SUPPORTING INFORMATION AND 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><b>Effective Date: April 5, 2004</b></p> <p><b>Implementation Date: April 5, 2004</b></p> <p><b>Pre-Implementation Contact(s): Jackie Sheridan-Moore (410) 786-4635</b></p> <p><b>Post-Implementation Contact(s): Jackie Sheridan-Moore 410-786-4635</b></p>	<p><b>These instructions should be implemented within your current operating budget.</b></p>
---	--

## Attachment - Recurring Update Notification

Pub. 100-04	Transmittal: 71	Date: January 23, 2004	Change Request 3072
-------------	-----------------	------------------------	---------------------

**SUBJECT: Changes to the Laboratory National Coverage Determination (NCD) Edit Software for April 2004**

### I. GENERAL INFORMATION

**A. Background:** This transmittal announces the changes that will be included in the April 2004 release of the edit module for clinical diagnostic laboratory services. 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 Science Corporation and incorporated in the shared systems so that laboratory claims subject to one of the 23 NCDs are processed uniformly throughout the nation effective January 1, 2003. The laboratory edit module for the NCDs will be updated quarterly as necessary to reflect ministerial coding updates and substantive changes to the NCDs developed through the NCD process. (See Pub. 100-4, Chapter 16, §120.2.)

### B. Policy:

1. In accordance with the decision memorandum published on the coverage Internet site on October 30, 2003 (see <http://cms.hhs.gov/mcd/viewdecisionmemo.asp?id=99>), we are adding the following diagnosis codes to the list of "ICD-9-CM Codes Covered by Medicare" for the serum iron studies NCD:

- 403.01, Hypertensive renal disease, malignant, with renal failure
- 403.11, Hypertensive renal disease, benign, with renal failure
- 403.91, Hypertensive renal disease, unspecified, with renal failure
- 404.02, Hypertensive heart and renal disease, malignant, with renal failure
- 404.03, Hypertensive heart and renal disease, malignant, with heart and renal failure
- 404.12, Hypertensive heart and renal disease, benign, with renal failure
- 404.13, Hypertensive heart and renal disease, benign, with heart and renal failure
- 404.92, Hypertensive heart and renal disease, unspecified, with renal failure
- 404.93, Hypertensive heart and renal disease, unspecified, with heart and renal failure

These codes will be covered for services furnished on or after April 5, 2004.

**C. Provider Education:** Intermediaries and/or carriers shall inform affected providers by posting either a summary or relevant portions of this document on their Web site by [insert date 2 weeks after publication.] Also, intermediaries and/or carriers shall publish

this same information in their next regularly scheduled bulletin. If they have a listserv that targets affected providers, they shall use it to notify subscribers about the changes to the laboratory edit software for April 5, 2004 that is available on their Web sites.

**II. BUSINESS REQUIREMENTS**

*"Shall" denotes a mandatory requirement*

*"Should" denotes an optional requirement*

<b>Requirement #</b>	<b>Requirements</b>	<b>Responsibility</b>
3072.1	The laboratory edit module developer contractor shall modify the edit software as discussed in the policy section above.	CSC
3072.2	The module developer shall make the revised software available to down load from the CMS data center via connect:direct. CSC shall notify the shared system maintainers of the data set names via email.	CSC
3072.3	CMS shall make corresponding changes to the NCD coding manual and the NCDs posted on the Internet.	CMS
3072.4	The shared system maintainers shall install the revised edit module after testing and distribute it to the carriers and intermediaries as part of their routine release.	All SSMs
3072.5	Carriers and intermediaries shall conduct provider education as directed above to advise laboratories changes to the laboratory edit module.	All carriers and FIs

**III. SUPPORTING INFORMATION & POSSIBLE DESIGN CONSIDERATIONS**

**A. Other Instructions: N/A**

<b>X-Ref Requirement #</b>	<b>Instructions</b>

**B. Design Considerations: N/A**

<b>X-Ref Requirement #</b>	<b>Recommendation for Medicare System Requirements</b>

**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><b>Effective Date: April 5, 2004</b></p> <p><b>Implementation Date: April 5, 2004</b></p> <p><b>Pre-Implementation Contact:</b> Jackie Sheridan-Moore at (410) 786-4635 or at <a href="mailto:jsheridan@cms.hhs.gov">jsheridan@cms.hhs.gov</a>.</p>	<p><b>These instructions shall be implemented within your current operating budget.</b></p> <p><b>Post-Implementation Contact:</b> Jackie Sheridan-Moore at 410-786-4635 or at <a href="mailto:jsheridan@cms.hhs.gov">jsheridan@cms.hhs.gov</a>.</p>
--	--

# Medicare Claims Processing Manual

## Chapter 16 - Laboratory Services

---

### Table of Contents

*(Rev. 71, 01-23-04)*

#### 120- Clinical Laboratory Services Based on the Negotiated Rulemaking

##### 120.1 - Negotiated Rulemaking Implementation

*120.2 – Implementation and Updates of Negotiated National Coverage Determinations (NCDs) or Clinical Diagnostic Laboratory Services*

## ***120.2 Implementation and Updates of Negotiated National Coverage Determinations (NCDs) for Clinical Diagnostic Laboratory Services***

***(Rev. 71, 01-23-04)***

*Under a negotiated rulemaking process, the Center for Medicare & Medicaid Services (CMS) developed 23 NCDs for clinical diagnostic laboratory services. The NCDs are applicable to services billed under Part B regardless of the entity providing the services. Thus, they are binding on carriers and fiscal intermediaries in processing clinical diagnostic laboratory services on an outpatient basis.*

*In order to ensure uniformity in the implementation of the NCDs, CMS developed the NCDs utilizing three lists of ICD-9-CM diagnosis codes. Every ICD-9-CM diagnosis code will fall into one of the three lists. The lists included: ICD-9-CM Codes Covered by Medicare, ICD-9-CM Codes Denied, and ICD-9-CM Codes That Do Not Support Medical Necessity.*

*The CMS has contracted with Computer Sciences Corporation (CSC) to develop national uniform software to implement these negotiated NCDs. This software, called the laboratory edit module, was developed and incorporated in the shared systems so that laboratory claims subject to one of the 23 NCDs are processed uniformly throughout the nation effective January 1, 2003.*

*In addition, the NCDs are maintained through the NCD process that was announced in the "Federal Register" on September 26, 2003 (68 FR 55634). This process provides for public participation through a comment period at the beginning of the evaluation of the issue and includes a detailed decision document that outlines the rationale for the decision. These documents may be viewed on the Medicare coverage homepage at [cms.hhs.gov/coverage](http://cms.hhs.gov/coverage).*

*On a quarterly basis, CMS will update the NCD edit module as necessary for ministerial coding changes and to implement the NCD decisions described above. NCD changes are transmitted to CSC. CSC modifies the edit module software and communicates the software to the shared system maintainers using connect:direct. The shared system maintainers install the revised edit module after testing and distribute it to the carriers and intermediaries (FIs) as part of their routine release. Carrier and FIs will conduct provider education to advise the laboratories of changes to the laboratory edit module quarterly.*