CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10877	<b>Date: July 15, 2021</b>
	Change Request 12384

# SUBJECT: Changes to the Laboratory National Coverage Determination [NCD] Edit Software for October 2021

**I. SUMMARY OF CHANGES:** This Change Request (CR) announces the changes that will be included in the October 2021 quarterly release of the edit module for clinical diagnostic laboratory services. This Recurring Update Notification applies to Chapter 16, Section 120.2, Publication 100-04.

#### EFFECTIVE DATE: October 1, 2021 - Unless noted differently in requirements.

\*Unless otherwise specified, the effective date is the date of service.

**IMPLEMENTATION DATE: October 4, 2021** 

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. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

# **II. CHANGES IN MANUAL INSTRUCTIONS:** (N/A if manual is not updated) R=REVISED, N=NEW, D=DELETED-*Only One Per Row*.

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

#### III. FUNDING:

#### For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

#### **IV. ATTACHMENTS:**

**Recurring Update Notification** 

## **Attachment - Recurring Update Notification**

Pub. 100-04	Transmittal:10877	<b>Date: July 15, 2021</b>	<b>Change Request: 12384</b>
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SUBJECT: Changes to the Laboratory National Coverage Determination [NCD] Edit Software for October 2021

EFFECTIVE DATE: October 1, 2021 - Unless noted differently in requirements.

\*Unless otherwise specified, the effective date is the date of service.

**IMPLEMENTATION DATE: October 4, 2021** 

#### I. GENERAL INFORMATION

- **A. Background:** This transmittal announces the changes that will be included in the October 2021 quarterly release of the edit module for clinical diagnostic laboratory services. The National Coverage Determinations (NCDs) for clinical diagnostic laboratory services were developed by the laboratory negotiated rulemaking committee, and the final rule was published on November 23, 2001. Nationally uniform software was developed and incorporated in the Medicare shared systems so that laboratory claims subject to one of the 23 NCDs (Publication 100-03, Sections 190.12 190.34) were processed uniformly throughout the nation, effective April 1, 2003.
- **B.** Policy: In accordance with Chapter 16, §120.2, Publication 100-04, the laboratory edit module is updated quarterly as necessary to reflect ministerial coding updates and substantive changes to the NCDs developed through the NCD process. The changes are a result of coding analysis decisions developed under the procedures for maintenance of codes in the negotiated NCDs and biannual updates of the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes. This instruction communicates requirements to Shared System Maintainers (SSMs) and contractors, notifying them of changes to the laboratory edit module to update it for changes in laboratory NCD code lists for October 2021. Please access the link below for the NCD spreadsheet included with this change request:

https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/October2021.zip

#### II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
			A/B	}	D	5	Sha	red-		Other
		1	MAC	$\mathbb{C}$	M	,	Sys	tem		
					Е	Ma	aint	aine	ers	
		A	В	Н		F	M	V	C	
				Н	M	I	C	M	W	
				Н	A	S	S	S	F	
					С	S				
12384.1	The module developer shall delete ICD-10 CM code									Fu Associates
	provided in the link effective 9/30/2021 from the list									
	of ICD-10-CM codes that are covered by Medicare for									
	the Urine Culture, Bacterial (190.12) NCD.									
1000111										
12384.1.1	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2021 to the list of									
	ICD-10-CM codes that are covered by Medicare for									

Number	Requirement	Re	espo	nsil	bilit	V				
			A/B ИА(	3	D M E		Sys	red- tem		Other
		A	В	H H H	M A C	F I S	M C S	V M S	C W F	
	the Urine Culture, Bacterial (190.12) NCD.									
12384.2	The module developer shall delete ICD-10 CM codes provided in the link effective 9/30/2021 from the list of ICD-10-CM codes that are covered by Medicare for the Human Immunodeficiency Virus (HIV) Testing (Diagnosis) (190.14) NCD.									Fu Associates
12384.2.1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2021 to the list of ICD-10-CM codes that are covered by Medicare for the Human Immunodeficiency Virus (HIV) Testing (Diagnosis) (190.14) NCD.									Fu Associates
12384.3	The module developer shall delete ICD-10 CM codes provided in the link effective 9/30/2021 from the list of ICD-10-CM codes that are not medically necessary for the Blood Counts (190.15) NCD.									Fu Associates
12384.4	The module developer shall delete ICD-10 CM codes provided in the link effective 9/30/2021 from the list of ICD-10-CM codes that are covered by Medicare for the Partial Thromboplastin Time (PTT) (190.16) NCD.									Fu Associates
12384.4.1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2021 to the list of ICD-10-CM codes that are covered by Medicare for the Partial Thromboplastin Time (PTT) (190.16) NCD.									Fu Associates
12384.5	The module developer shall delete ICD-10 CM codes provided in the link effective 9/30/2021 from the list of ICD-10-CM codes that are covered by Medicare for the Prothrombin Time (PT) (190.17) NCD.									Fu Associates
12384.5.1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2021 to the list of ICD-10-CM codes that are covered by Medicare for the Prothrombin Time (PT) (190.17) NCD.									Fu Associates
12384.6	The module developer shall delete ICD-10 CM code provided in the link effective 9/30/2021 from the list of ICD-10-CM codes that are covered by Medicare for the Serum Iron Studies (190.18) NCD.									Fu Associates

Number	Requirement	Responsibility								
		A/B D Shared-						Other		
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		_	Ъ		Е			aine		
		A	В	H H	M	F I	M C		C W	
				Н	A	S	S	S	F	
					С	S				
12384.6.1	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2021 to the list of ICD-10-CM codes that are covered by Medicare for									
	the Serum Iron Studies (190.18) NCD.									
12384.7	The module developer shall delete ICD-10 CM code									Fu Associates
	provided in the link effective 9/30/2021 from the list of ICD-10-CM codes that are covered by Medicare for									
	the Blood Glucose Testing (190.20A) NCD.									
	<u> </u>									
12384.7.1	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2021 to the list of ICD-10-CM codes that are covered by Medicare for									
	the Blood Glucose Testing (190.20A) NCD.									
	5 (									
12384.8	The module developer shall delete ICD-10 CM code									Fu Associates
	provided in the link effective 9/30/2021 from the list of ICD-10-CM codes that are covered by Medicare for									
	the Blood Glucose Testing (190.20B) NCD.									
	8(****)									
12384.8.1	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2021 to the list of ICD-10-CM codes that are covered by Medicare for									
	the Blood Glucose Testing (190.20B) NCD.									
12384.9	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2021 to the list of ICD-10-CM codes that are covered by Medicare for									
	the Tumor Antigen by Immunoassay CA 125 (190.28)									
	NCD.									
1020410										F. A.
12384.10	The module developer shall delete ICD-10 CM codes provided in the link effective 9/30/2021 from the list									Fu Associates
	of ICD-10-CM codes that are covered by Medicare for									
	the Gamma Glutamyl Transferase (190.32) NCD.									
1000411										F. A.
12384.11	The module developer shall delete ICD-10 CM code provided in the link effective 9/30/2021 from the list									Fu Associates
	of ICD-10-CM codes that are covered by Medicare for									
	the Hepatitis Panel/Acute Hepatitis Panel (190.33)									
	NCD.									
12384.11.	The module developer shall add ICD-10 CM codes									Fu Associates
12307.11.	provided in the link effective 10/1/2021 to the list of									1 u Associates
	ICD-10-CM codes that are covered by Medicare for									
	the Hepatitis Panel/Acute Hepatitis Panel (190.33)									

Number	Requirement	Responsibility								
			A/B MA(	3	D M	1	Sys	red- tem		Other
		A	В	H H	Е М	F	aint M C	aine V M	С	
				Н	A C	S S	S	S	F	
	NCD.									
12384.12	The module developer shall delete ICD-10 CM code provided in the link effective 9/30/2021 from the list of ICD-10-CM codes that are covered by Medicare for the Fecal Occult Blood Test (190.34) NCD.									Fu Associates
12384.12.	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2021 to the list of ICD-10-CM codes that are covered by Medicare for the Fecal Occult Blood Test (190.34) NCD.									Fu Associates
12384.13	The module developer shall provide the revised software as a mainframe (i.e., load module) to CMS to be distributed to the Shared System Maintainers (SSMs).									Fu Associates
12384.14	The SSMs shall install the edit module after testing and distribute it to the contractors as part of their routine release.					X	X			

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Re	espo	nsib	ility	,
			A/B MA(		D M E	C E D
		A	В	H H H	M A C	Ι
12384.15	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the "MLN Matters" listsery to get article release notifications, or review them in the MLN Connects weekly newsletter.	X	X			

### IV. SUPPORTING INFORMATION

#### Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref	Recommendations or other supporting information:
Requirement	
Number	

#### Section B: All other recommendations and supporting information: N/A

#### V. CONTACTS

**Pre-Implementation Contact(s):** Kimberly Long, 410-786-5702 or kimberly.long@cms.hhs.gov, Patricia Brocato-Simons, 410-786-0261 or patricia.brocatosimons@cms.hhs.gov, Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR).

#### VI. FUNDING

#### **Section A: For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**ATTACHMENTS: 0**