CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 4400	Date: September 27, 2019
	Change Request 11485

# SUBJECT: Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2020

**I. SUMMARY OF CHANGES:** This Change Request (CR) announces the changes that will be included in the January 2020 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, 2019 - Unless otherwise indicated in requirements** \*Unless otherwise specified, the effective date is the date of service. **IMPLEMENTATION DATE: January 6, 2020** 

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. 100-04Transmittal: 4400Date: September 27, 2019Change Request: 11485

SUBJECT: Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2020

**EFFECTIVE DATE:** October 1, 2019 - Unless otherwise indicated in requirements \*Unless otherwise specified, the effective date is the date of service. IMPLEMENTATION DATE: January 6, 2020

### I. GENERAL INFORMATION

**A. Background:** This transmittal announces the changes that will be included in the January 2020 quarterly release of the edit module for clinical diagnostic laboratory services. The laboratory negotiated rulemaking committee developed the National Coverage Determinations (NCDs) for clinical diagnostic laboratory services, 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 January 2020. Please access the link below for the NCD spreadsheet included with this change request:

https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/January2020.zip

### II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Re	espo	nsil	bilit	y				
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11485.1	The module developer shall provide the revised									Fu Associates
	software as a mainframe (i.e., load module) to CMS to be distributed to the SSMs.									
	be distributed to the SSIVIS.									
11485.2	The SSMs shall install the edit module after testing					Х	Х			
	and distribute it to the contractors as part of their									
	routine release.									

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

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11485.3	Contractors shall adjust claims brought to their attention. Contractors do not need to search their files to either retract payment for claims already paid or retroactively pay claims.	X	X							
11485.4	The module developer shall delete the ICD-10 CM code provided in the link effective 9/30/2019 from the list of ICD-10-CM codes that are covered by Medicare for the Urine Culture, Bacterial (190.12) NCD.									Fu Associates
11485.4.1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are covered by Medicare for the Urine Culture, Bacterial (190.12) NCD.									Fu Associates
11485.4.2	The module developer shall add the ICD-10 CM code provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are denied by Medicare for the Urine Culture, Bacterial (190.12) NCD.									Fu Associates
11485.5	The module developer shall add the ICD-10 CM code provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are denied by Medicare for the Human Immunodeficiency Virus (HIV)Testing (Prognosis Including Monitoring) (190.13) NCD.									Fu Associates
11485.6	The module developer shall add the ICD-10 CM code provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are denied by Medicare for the Human Immunodeficiency Virus (HIV) Testing (Diagnosis) (190.14) NCD.									Fu Associates
11485.7	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are not medically necessary for the Blood Counts (190.15) NCD.									Fu Associates
11485.7.1	The module developer shall delete the ICD-10 CM code provided in the link effective 9/30/2019 from the list of ICD-10-CM codes that are not medically necessary for the Blood Counts (190.15) NCD.									Fu Associates
11485.7.2	The module developer shall add the ICD-10 CM code provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are denied by Medicare for the Blood Counts (190.15) NCD.									Fu Associates

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11485.8	The module developer shall delete ICD-10 CM codes provided in the link effective 9/30/2019 from the list of ICD-10-CM codes that are covered by Medicare for the Partial Thromboplastin Time (PTT) (190.16) NCD.									Fu Associates
11485.8.1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are covered by Medicare for the Partial Thromboplastin Time (PTT) (190.16) NCD.									Fu Associates
11485.8.2	The module developer shall add the ICD-10 CM code provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are denied by Medicare for the Partial Thromboplastin Time (PTT) (190.16) NCD.									Fu Associates
11485.9	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are covered by Medicare for the Prothrombin Time (PT) (190.17) NCD.									Fu Associates
11485.9.1	The module developer shall delete ICD-10 CM codes provided in the link effective 9/30/2019 from the list of ICD-10-CM codes that are covered by Medicare for the Prothrombin Time (PT) (190.17) NCD.									Fu Associates
11485.9.2	The module developer shall add the ICD-10 CM code provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are denied by Medicare for the Prothrombin Time (PT) (190.17) NCD.									Fu Associates
11485.10	The module developer shall delete ICD-10 CM codes provided in the link effective 9/30/2019 from the list of ICD-10-CM codes that are covered by Medicare for the Serum Iron Studies (190.18) NCD.									Fu Associates
11485.10. 1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are covered by Medicare for the Serum Iron Studies (190.18) NCD.									Fu Associates
11485.10. 2	The module developer shall add the ICD-10 CM code provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are denied by Medicare for the Serum Iron Studies (190.18) NCD.									Fu Associates

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		of ICD-10-CM codes that are covered by Medicare for									
the Thyroid Testing (190.22) NCD.		the Thyroid Testing (190.22) NCD.									
11485.15. The module developer shall add ICD-10 CM codes Image: Code state st	11/05 15	The module developer shall add ICD 10 CM and an									En Associatas
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ICD-10-CM codes that are covered by Medicare for	1										
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Number	Requirement	Re	espo	onsi	bilit	y				
			A/B MA(	3	D M E		Sys	red- tem		Other
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11485.15. 2	The module developer shall add the ICD-10 CM code provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are denied by Medicare for the Thyroid Testing (190.22) NCD.									Fu Associates
11485.16	The module developer shall add the ICD-10 CM code provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are denied by Medicare for the Lipids Testing (190.23A) NCD.									Fu Associates
11485.17	The module developer shall add the ICD-10 CM code provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are denied by Medicare for the Lipids Testing (190.23B) NCD.									Fu Associates
11485.18	The module developer shall delete ICD-10 CM codes provided in the link effective 9/30/2019 from the list of ICD-10-CM codes that are covered by Medicare for the Digoxin Therapeutic Drug Assay (190.24) NCD.									Fu Associates
11485.18. 1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are covered by Medicare for the Digoxin Therapeutic Drug Assay (190.24) NCD.									Fu Associates
11485.18. 2	The module developer shall add the ICD-10 CM code provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are denied by Medicare for the Digoxin Therapeutic Drug Assay (190.24) NCD.									Fu Associates
11485.19	The module developer shall add the ICD-10 CM code provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are denied by Medicare for the Alpha-fetoprotein (190.25) NCD.									Fu Associates
11485.19. 1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are covered by Medicare for the Alpha-fetoprotein (190.25) NCD.									Fu Associates
11485.20	The module developer shall add the ICD-10 CM code provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are denied by Medicare for the Carcinoembryonic Antigen (190.26) NCD.									Fu Associates
11485.20. 1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2019 to the list of									Fu Associates

Number	Requirement	Re	espo	nsi	bilit	v				
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	ICD-10-CM codes that are covered by Medicare for the Carcinoembryonic Antigen (190.26) NCD.									
11485.21	The module developer shall add the ICD-10 CM code provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are denied by Medicare for the Human Chorionic Gonadotropin (190.27) NCD.									Fu Associates
11485.21.	The module developer shall add the ICD-10 CM code									Fu Associates
1	provided in the link effective $10/1/2019$ to the list of									1 4 1 1550014105
	ICD-10-CM codes that are covered by Medicare for the Human Chorionic Gonadotropin (190.27) NCD.									
11485.22	The module developer shall add the ICD-10 CM code	1								Fu Associates
	provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are denied by Medicare for the Tumor Antigen by Immunoassay CA 125 (190.28) NCD.									
11485.23	The module developer shall add the ICD-10 CM code									Fu Associates
11403.23	provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are denied by Medicare for the Tumor Antigen by Immunoassay CA 15-3/CA 27.29 (190.29) NCD.									Tu Associates
11485.23.	The module developer shall add ICD-10 CM codes									Fu Associates
1	provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are covered by Medicare for the Tumor Antigen by Immunoassay CA 15-3/CA 27.29 (190.29) NCD.									
11485.24	The module developer shall add the ICD-10 CM code									Fu Associates
	provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are denied by Medicare for the Tumor Antigen by Immunoassay CA 19-9 (190.30) NCD.									
11485.25	The module developer shall add the ICD-10 CM code									Fu Associates
	provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are denied by Medicare for the Prostate Specific Antigen (190.31) NCD.									
11485.26	The module developer shall add ICD-10 CM codes	1								Fu Associates
	provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are covered by Medicare for the Gamma Glutamyl Transferase (190.32) NCD.									
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Number	Requirement	R	espo	onsi	bilit	y				
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11485.26. 1	The module developer shall add the ICD-10 CM code provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are denied by Medicare for the Gamma Glutamyl Transferase (190.32) NCD.									Fu Associates
11485.27	The module developer shall add the ICD-10 CM code provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are covered by Medicare for the Hepatitis Panel/Acute Hepatitis Panel (190.33) NCD.									Fu Associates
11485.27. 1	The module developer shall add the ICD-10 CM code provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are denied by Medicare for the Hepatitis Panel/Acute Hepatitis Panel (190.33) NCD.									Fu Associates
11485.28	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are covered by Medicare for the Fecal Occult Blood Test (190.34) NCD.									Fu Associates
11485.28. 1	The module developer shall add the ICD-10 CM code provided in the link effective 10/1/2019 to the list of ICD-10-CM codes that are denied by Medicare for the Fecal Occult Blood Test (190.34) NCD.									Fu Associates

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Re	spo	nsib	ility	
			A/B MAC		D M E	C E D
		A	В	H H H	M A C	Ι
11485.29	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" listserv to get	X	X			

Number	Requirement	Re	espo	nsib	ility	
			A/B		D	C
		1	MA	Ċ	M E	E D
		Α	В	H H	M	Ι
				H	A C	
	article release notifications, or review them in the MLN Connects weekly newsletter.					

### 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):** Patricia Brocato-Simons, 410-786-0261 or patricia.brocatosimons@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**