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

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
11485.1	The module developer shall provide the revised software as a mainframe (i.e., load module) to CMS to be distributed to the SSMs.									Fu Associates
11485.2	The SSMs shall install the edit module after testing and distribute it to the contractors as part of their routine release.					X	X			

Number	Requirement	Responsibility								Other
		A/B MAC			D M E M A C	Shared-System Maintainers				
		A	B	H H H		F I S S	M C S	V M S	C W F	
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

Number	Requirement	Responsibility								Other
		A/B MAC			D M E MAC	Shared-System Maintainers				Other
		A	B	H H H		F I S S	M C S	V M S	C W F	
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

Number	Requirement	Responsibility								Other
		A/B MAC			D M E MAC	Shared-System Maintainers				Other
		A	B	H H H		F I S S	M C S	V M S	C W F	
11485.11	The module developer shall add the ICD-10 CM code effective 10/1/2019 to the list of ICD-10-CM codes that are denied by Medicare for the Collagen Crosslinks, Any Method (190.19) NCD.									Fu Associates
11485.12	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 Blood Glucose Testing (190.20A) NCD.									Fu Associates
11485.12. 1	The module developer shall add 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 Glucose Testing (190.20A) NCD.									Fu Associates
11485.13	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 Blood Glucose Testing (190.20B) NCD.									Fu Associates
11485.13. 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 Blood Glucose Testing (190.20B) NCD.									Fu Associates
11485.14	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 Glycated Hemoglobin/Glycated Protein (190.21) NCD.									Fu Associates
11485.14. 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 Glycated Hemoglobin/Glycated Protein (190.21) NCD.									Fu Associates
11485.15	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 Thyroid Testing (190.22) NCD.									Fu Associates
11485.15. 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 Thyroid Testing (190.22) NCD.									Fu Associates

Number	Requirement	Responsibility								
		A/B MAC			D M E M A C	Shared-System Maintainers				Other
		A	B	H H H		F I S S	M C S	V M S	C W F	
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	Responsibility								Other
		A/B MAC			D M E M A C	Shared-System Maintainers				Other
		A	B	H H H		F I S S	M C S	V M S	C W F	
	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. 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 covered by Medicare for the Human Chorionic Gonadotropin (190.27) NCD.									Fu Associates
11485.22	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 Tumor Antigen by Immunoassay CA 125 (190.28) NCD.									Fu Associates
11485.23	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 Tumor Antigen by Immunoassay CA 15-3/CA 27.29 (190.29) NCD.									Fu Associates
11485.23. 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 Tumor Antigen by Immunoassay CA 15-3/CA 27.29 (190.29) NCD.									Fu Associates
11485.24	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 Tumor Antigen by Immunoassay CA 19-9 (190.30) NCD.									Fu Associates
11485.25	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 Prostate Specific Antigen (190.31) NCD.									Fu Associates
11485.26	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 Gamma Glutamyl Transferase (190.32) NCD.									Fu Associates

Number	Requirement	Responsibility								
		A/B MAC			D M E	Shared-System Maintainers				Other
		A	B	H H H	M A C	F I S S	M C S	V M S	C W F	
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	Responsibility				
		A/B MAC			D M E	C E D I
		A	B	H H H	M A C	
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	Responsibility				
		A/B MAC			D M E M A C	C E D I
		A	B	H H H		
	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 Requirement Number	Recommendations or other supporting information:

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