CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 4139	Date: September 28, 2018
	Change Request 10941

SUBJECT: Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2019

I. SUMMARY OF CHANGES: This Change Request (CR) announces the changes that will be included in the January 2019 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: January 1, 2019 - Unless noted differently in requirements.

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

IMPLEMENTATION DATE: January 7, 2019

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

SUBJECT: Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2019

EFFECTIVE DATE: January 1, 2019 - Unless noted differently in requirements.

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

IMPLEMENTATION DATE: January 7, 2019

I. GENERAL INFORMATION

- **A. Background:** This transmittal announces the changes that will be included in the January 2019 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 January 2019. Please access the link below for the NCD spreadsheets included with this change request:

https://www.cms.gov/medicare/coverage/determinationprocess/downloads/January2019.zip

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
			A/B	}	D	Shared-				Other
		1	MA	\mathbb{C}	M	1 System				
					Е	Maintainers			ers	
		A	В	Н		F	M	V	C	
				Н	M	Ι	C	M	W	
				Н	A	S	S	S	F	
					C	S				
10941.1	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.									
10941.2	The SSMs shall install the edit module after testing					X	X			
	and distribute it to the contractors as part of their									

Number	Requirement	Re	espo	nsi	bilit	·V				
THE	Requirement		а <u>вро</u> А/В ИА(3	D M E	ı	Sys	red- tem		Other
		A	В	H H H	M A C	F	M C S	V	С	
	routine release.									
10941.3	Contractors shall adjust claims brought to their attention. Contractors do not need to search their files either to retract payment for claims already paid or retroactively pay claims.	X	X							
10941.4	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 to the list of ICD-10-CM codes that are covered by Medicare for the Urine Culture, Bacterial (190.12) NCD.									Fu Associates
10941.4.1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 to the list of ICD-10-CM codes that are denied by Medicare for the Urine Culture, Bacterial (190.12) NCD.									Fu Associates
10941.5	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 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
10941.6	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 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
10941.6.1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 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
10941.7	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 to the list of ICD-10-CM codes that are not medically necessary for the Blood Counts (190.15) NCD.									Fu Associates
10941.7.1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 to the list of ICD-10-CM codes that are denied by Medicare for the Blood Counts (190.15) NCD.									Fu Associates
10941.8	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 to the list of									Fu Associates

Number	r Requirement Responsibility									
			A/B						Other	
		N	ИAO	\mathbb{C}	M		•	tem		
					Е			aine		
		Α	В	H H	M	F I	M C		C W	
				Н	A	S	S	S	F	
					C	S			_	
	ICD-10-CM codes that are covered by Medicare for									
	the Partial Thromboplastin Time (PTT) (190.16) NCD.									
10941.8.1	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2018 to the list of ICD-10-CM codes that are denied by Medicare for the									
	Partial Thromboplastin Time (PTT) (190.16) NCD.									
10941.9	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2018 to the list of									
	ICD-10-CM codes that are covered by Medicare for the Prothrombin Time (PT) (190.17) NCD.									
10941.9.1	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2018 to the list of									
	ICD-10-CM codes that are denied by Medicare for the Prothrombin Time (PT) (190.17) NCD.									
	Flouitoilioni Time (F1) (190.17) NCD.									
10941.10	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2018 to the list of									
	ICD-10-CM codes that are covered by Medicare for the Serum Iron Studies (190.18) NCD.									
10941.10.	The module developer shall add ICD-10 CM codes									Fu Associates
1	provided in the link effective 10/1/2018 to the list of									
	ICD-10-CM codes that are denied by Medicare for the									
	Serum Iron Studies (190.18) NCD.									
10941.11	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2018 to the list of									
	ICD-10-CM codes that are covered by Medicare for the Collagen Crosslinks, Any Method (190.19) NCD.									
10941.11.	The module developer shall add ICD-10 CM codes									Fu Associates
1	provided in the link effective 10/1/2018 to the list of ICD-10-CM codes that are denied by Medicare for the									
	Collagen Crosslinks, Any Method (190.19) NCD.									
10941.12	The module developer shall add ICD-10 CM codes									Fu Associates
107 11.12	provided in the link effective 10/1/2018 to the list of									2 6 7 1550014105
	ICD-10-CM codes that are covered by Medicare for									
	the Blood Glucose Testing (190.20A) NCD.									
10941.12.	The module developer shall add ICD-10 CM codes									Fu Associates
1	provided in the link effective 10/1/2018 to the list of									
	ICD-10-CM codes that are denied by Medicare for the									

Number	Requirement Responsibility									
			A/B MA(D M E	ı	Sys	red- tem aine		Other
		A	В	H H H	M A C	F I S	M C S	V M S	C W F	
	Blood Glucose Testing (190.20A) NCD.									
10941.13	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 to the list of ICD-10-CM codes that are covered by Medicare for the Blood Glucose Testing (190.20B) NCD.									Fu Associates
10941.13.	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 to the list of ICD-10-CM codes that are denied by Medicare for the Blood Glucose Testing (190.20B) NCD.									Fu Associates
10941.14	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 to the list of ICD-10-CM codes that are covered by Medicare for the Glycated Hemoglobin/Glycated Protein (190.21) NCD.									Fu Associates
10941.14.	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 to the list of ICD-10-CM codes that are denied by Medicare for the Glycated Hemoglobin/Glycated Protein (190.21) NCD.									Fu Associates
10941.15	The module developer shall add ICD-10 CM code provided in the link effective 10/1/2017 to the list of ICD-10-CM codes that are covered by Medicare for the Thyroid Testing (190.22) NCD.									Fu Associates
10941.15. 1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 to the list of ICD-10-CM codes that are covered by Medicare for the Thyroid Testing (190.22) NCD.									Fu Associates
10941.15. 2	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 to the list of ICD-10-CM codes that are denied by Medicare for the Thyroid Testing (190.22) NCD.									Fu Associates
10941.16	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 to the list of ICD-10-CM codes that are covered by Medicare for the Lipids Testing (190.23A) NCD.									Fu Associates
10941.16. 1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 to the list of ICD-10-CM codes that are denied by Medicare for the									Fu Associates

Number	Requirement Responsibility									
			А/В ИА(D M E		Sys	red- tem aine		Other
		A	В	H H H	M A C	F I S	M C S	V M S	C W F	
	Lipids Testing (190.23A) NCD.					~				
10941.17	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 to the list of ICD-10-CM codes that are covered by Medicare for the Lipids Testing (190.23B) NCD.									Fu Associates
10941.17. 1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 to the list of ICD-10-CM codes that are denied by Medicare for the Lipids Testing (190.23B) NCD.									Fu Associates
10941.18	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 to the list of ICD-10-CM codes that are covered by Medicare for the Digoxin Therapeutic Drug Assay (190.24) NCD.									Fu Associates
10941.18.	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 to the list of ICD-10-CM codes that are denied by Medicare for the Digoxin Therapeutic Drug Assay (190.24) NCD.									Fu Associates
10941.19	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 to the list of ICD-10-CM codes that are covered by Medicare for the Alpha-fetoprotein (190.25) NCD.									Fu Associates
10941.19.	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 to the list of ICD-10-CM codes that are denied by Medicare for the Alpha-fetoprotein (190.25) NCD.									Fu Associates
10941.20	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 to the list of ICD-10-CM codes that are covered by Medicare for the Carcinoembryonic Antigen (190.26) NCD.									Fu Associates
10941.20.	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 to the list of ICD-10-CM codes that are denied by Medicare for the Carcinoembryonic Antigen (190.26) NCD.									Fu Associates
10941.21	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 to the list of ICD-10-CM codes that are covered by Medicare for the Human Chorionic Gonadotropin (190.27) NCD.									Fu Associates

Number	er Requirement Responsibility									
110111001	1. Company		A/B		D		Sha	red-		Other
			ΛA		M		System			5 3333
					Е		•	aine		
		Α	В	Н		F	M	V	С	
				Н	M	I	C		W	
				Н	A	S	S	S	F	
					C	S				
10941.21.	The module developer shall add ICD-10 CM codes									Fu Associates
1	provided in the link effective 10/1/2018 to the list of									
	ICD-10-CM codes that are denied by Medicare for the									
	Human Chorionic Gonadotropin (190.27) NCD.									
10941.22	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2018 to the list of									
	ICD-10-CM codes that are denied by Medicare for the									
	Tumor Antigen by Immunoassay CA 125 (190.28)									
	NCD.									
10941.23	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2018 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.									
10941.23.	The module developer shall add ICD-10 CM codes									Fu Associates
1	provided in the link effective 10/1/2018 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.									
10941.24	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2018 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.									
10941.25	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2018 to the list of									
	ICD-10-CM codes that are denied by Medicare for the									
	Prostate Specific Antigen (190.31) NCD.									
10941.26	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2018 to the list of									
	ICD-10-CM codes that are covered by Medicare for									
	the Gamma Glutamyl Transferase (190.32) NCD.									
10941.26.	The module developer shall add ICD-10 CM codes									Fu Associates
1	provided in the link effective 10/1/2018 to the list of									
	ICD-10-CM codes that are denied by Medicare for the									
	Gamma Glutamyl Transferase (190.32) NCD.									
10941.27	The module developer shall add ICD-10 CM code									Fu Associates
	provided in the link effective 10/1/2018 to the list of									
	ICD-10-CM codes that are covered by Medicare for									

Number	Requirement	Re	espo	nsil	bilit	v				
			А/В ИА(D M E		Sys	red- tem		Other
		A	В	H H H	M A C	F I S S	M C S		C W F	
	the Hepatitis Panel/Acute Hepatitis Panel (190.33) NCD.									
10941.27.	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 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
10941.28	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 to the list of ICD-10-CM codes that are covered by Medicare for the Fecal Occult Blood Test (190.34) NCD.									Fu Associates
10941.28. 1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2018 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	spoi	nsib	ility	
			A/B MA(D M E	C E D
		A	В	H H H	M A C	Ι
10941.29	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 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:

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
	N/A

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

V. CONTACTS

Pre-Implementation Contact(s): Patti 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