CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11013	Date: October 1, 2021
	Change Request 12468

SUBJECT: Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2022

I. SUMMARY OF CHANGES: This Change Request (CR) announces the changes that will be included in the January 2022 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, 2022 - Unless noted differently in requirements.

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

IMPLEMENTATION DATE: January 3, 2022

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: 11013	Date: October 1, 2021	Change Request: 12468
I UD. IUU-UT	11ansimillai. 11vis	Date. October 1, 2021	Change Request. 12400

SUBJECT: Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2022

EFFECTIVE DATE: January 1, 2022 - Unless noted differently in requirements.

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

IMPLEMENTATION DATE: January 3, 2022

I. GENERAL INFORMATION

- **A. Background:** This transmittal announces the changes that will be included in the January 2022 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 2022. Please access the link below for the NCD spreadsheet included with this change request:

https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/January-2022.zip

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Re	spoi	nsibility	7					
		Α	A/B MAC		DME	Share	Shared-System Maintainers			Other
		Α	В	ННН		FISS	MCS	VMS	CWF	
					MAC					
12468.1	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 Urine Culture, Bacterial (190.12) NCD.									Fu Associates
12468.1.1	The module developer shall add the ICD-10									Fu Associates

Number	Requirement	Responsibility								
		A	/B 1	MAC	DME	Share	d-Syste	m Main	tainers	Other
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
	CM code provided in the link effective 1/1/2021 to the list of ICD-10-CM codes that are denied by Medicare for the Urine Culture, Bacterial (190.12) NCD.									
12468.2	The module developer shall add the ICD-10 CM code provided in the link effective 1/1/2021 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
12468.3	The module developer shall add the ICD-10 CM code provided in the link effective 1/1/2021 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
12468.4	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 not medically necessary for the Blood Counts (190.15) NCD.									Fu Associates
12468.4.1	The module developer shall add the ICD-10 CM code provided in the link effective 1/1/2021 to the list of ICD-10-CM codes that									Fu Associates

Number	Requirement	Responsibility								
		Α	/B 1	MAC	DME	Share	d-Syste	m Main	tainers	Other
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
	are denied by Medicare for the Blood Counts (190.15) NCD.									
12468.5	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
12468.5.1	The module developer shall add the ICD-10 CM code provided in the link effective 1/1/2021 to the list of ICD-10-CM codes that are denied by Medicare for the Partial Thromboplastin Time (PTT) (190.16) NCD.									Fu Associates
12468.6	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
12468.6.1	The module developer shall add the ICD-10 CM code provided in the link effective 1/1/2021 to the list of ICD-10-CM codes that are denied by Medicare for the Prothrombin Time (PT) (190.17) NCD.									Fu Associates
12468.7	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2021									Fu Associates

Number	Requirement	Responsibility								
		Α	/B I	MAC	DME	Share	d-Syste	m Maint	tainers	Other
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
	to the list of ICD-10-CM codes that are covered by Medicare for the Serum Iron Studies (190.18) NCD.				THE					
12468.7.1	The module developer shall add the ICD-10 CM code provided in the link effective 1/1/2021 to the list of ICD-10-CM codes that are denied by Medicare for the Serum Iron Studies (190.18) NCD.									Fu Associates
12468.8	The module developer shall add the ICD-10 CM code provided in the link effective 1/1/2021 to the list of ICD-10-CM codes that are denied by Medicare for the Collagen Crosslinks, Any Method (190.19) NCD.									Fu Associates
12468.9	The module developer shall add the ICD-10 CM code provided in the link effective 1/1/2021 to the list of ICD-10-CM codes that are covered by Medicare for the Blood Glucose Testing (190.20A) NCD.									Fu Associates
12468.9.1	The module developer shall add the ICD-10 CM code provided in the link effective 1/1/2021 to the list of ICD-10-CM codes that are denied by Medicare for the Blood Glucose Testing (190.20A) NCD.									Fu Associates
12468.9.2	The module developer shall add the ICD-10									Fu Associates

Number	Requirement	Responsibility								
		A	/B I	MAC	DME	Share	d-Syste	m Main	tainers	Other
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
	CM code 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.									
12468.10	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 Blood Glucose Testing (190.20B) NCD.									Fu Associates
12468.10.1	The module developer shall add the ICD-10 CM code provided in the link effective 1/1/2021 to the list of ICD-10-CM codes that are covered by Medicare for the Blood Glucose Testing (190.20B) NCD.									Fu Associates
12468.10.2	The module developer shall add the ICD-10 CM code provided in the link effective 1/1/2021 to the list of ICD-10-CM codes that are denied by Medicare for the Blood Glucose Testing (190.20B) NCD.									Fu Associates
12468.11	The module developer shall add ICD-10 CM codes provided in the link effective 1/1/2022 to the list of ICD-10-CM codes that are covered by Medicare for the Glycated Hemoglobin/Glycated									Fu Associates

Number	Requirement	Responsibility								ı
				MAC	DME		d-Syste			Other
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
	Protein (190.21) NCD.									
12468.11.1	The module developer shall add the ICD-10 CM code provided in the link effective 1/1/2021 to the list of ICD-10-CM codes that are denied by Medicare for the Glycated Hemoglobin/Glycated Protein (190.21) NCD.									Fu Associates
12468.12	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 Thyroid Testing (190.22) NCD.									Fu Associates
12468.12.1	The module developer shall add the ICD-10 CM code provided in the link effective 1/1/2021 to the list of ICD-10-CM codes that are denied by Medicare for the Thyroid Testing (190.22) NCD.									Fu Associates
12468.13	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 Lipids Testing (190.23A) NCD.									Fu Associates
12468.13.1	The module developer shall add the ICD-10 CM code provided in the link effective 1/1/2021 to the list of ICD-10-CM codes that are denied by Medicare for the Lipids Testing									Fu Associates

Number	Requirement	Responsibility								
				MAC	DME			m Main		Other
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
	(190.23A) NCD.									
12468.14	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 Lipids Testing (190.23B) NCD.									Fu Associates
12468.14.1	The module developer shall add the ICD-10 CM code provided in the link effective 1/1/2021 to the list of ICD-10-CM codes that are denied by Medicare for the Lipids Testing (190.23B) NCD.									Fu Associates
12468.15	The module developer shall add the ICD-10 CM code provided in the link effective 10/1/2021 to the list of ICD-10-CM codes that are covered by Medicare for the Digoxin Therapeutic Drug Assay (190.24) NCD.									Fu Associates
12468.15.1	The module developer shall add the ICD-10 CM code provided in the link effective 1/1/2021 to the list of ICD-10-CM codes that are denied by Medicare for the Digoxin Therapeutic Drug Assay (190.24) NCD.									Fu Associates
12468.16	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									Fu Associates

Number	Requirement	Responsibility								
		A	/B I	MAC	DME	Share	d-Syste	m Main	tainers	Other
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
	covered by Medicare for the Alpha-fetoprotein (190.25) NCD.				TVII TC					
12468.16.1	The module developer shall add the ICD-10 CM code provided in the link effective 1/1/2021 to the list of ICD-10-CM codes that are denied by Medicare for the Alphafetoprotein (190.25) NCD.									Fu Associates
12468.17	The module developer shall add the ICD-10 CM code provided in the link effective 10/1/2021 to the list of ICD-10-CM codes that are covered by Medicare for the Carcinoembryonic Antigen (190.26) NCD.									Fu Associates
12468.17.1	The module developer shall add the ICD-10 CM code provided in the link effective 1/1/2021 to the list of ICD-10-CM codes that are denied by Medicare for the Carcinoembryonic Antigen (190.26) NCD.									Fu Associates
12468.18	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 Chorionic Gonadotropin (190.27) NCD.									Fu Associates
12468.18.1	The module developer shall add the ICD-10 CM code provided in									Fu Associates

Number	Requirement	Responsibility								
		A	/B 1	MAC	DME	Share	d-Syste	m Main	tainers	Other
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
	the link effective 1/1/2021 to the list of ICD-10-CM codes that are denied by Medicare for the Human Chorionic Gonadotropin (190.27) NCD.									
12468.19	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 Tumor Antigen by Immunoassay CA 125 (190.28) NCD.									Fu Associates
12468.19.1	The module developer shall add the ICD-10 CM code provided in the link effective 1/1/2021 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
12468.20	The module developer shall add the ICD-10 CM code effective provided in the link 10/1/2021 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
12468.20.1	The module developer shall add the ICD-10 CM code provided in the link effective 1/1/2021 to the list of ICD-10-CM codes that are denied by Medicare for the Tumor Antigen									Fu Associates

Number	Requirement	Responsibility								
		A/B MAC DME Shared-System Maintainers			Other					
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
	by Immunoassay CA 15-3/CA 27.29 (190.29) NCD.				TVII 1C					
12468.21	The module developer shall add the ICD-10 CM code provided in the link effective 1/1/2021 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
12468.22	The module developer shall add the ICD-10 CM code provided in the link effective 1/1/2021 to the list of ICD-10-CM codes that are denied by Medicare for the Prostate Specific Antigen (190.31) NCD.									Fu Associates
12468.23	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 Gamma Glutamyl Transferase (190.32) NCD.									Fu Associates
12468.23.1	The module developer shall add the ICD-10 CM code provided in the link effective 1/1/2021 to the list of ICD-10-CM codes that are denied by Medicare for the Gamma Glutamyl Transferase (190.32) NCD.									Fu Associates
12468.24	The module developer shall add the ICD-10 CM code provided in the link effective									Fu Associates

Number	Requirement	Responsibility								
		A	A/B MAC DME Shared-Syste				m Main	tainers	Other	
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
	1/1/2021 to the list of ICD-10-CM codes that are denied by Medicare for the Hepatitis Panel/Acute Hepatitis Panel (190.33) NCD.				WITE					
12468.25	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
12468.25.1	The module developer shall add the ICD-10 CM code provided in the link effective 1/1/2021 to the list of ICD-10-CM codes that are denied by Medicare for the Fecal Occult Blood Test (190.34) NCD.									Fu Associates
12468.25.2	The module developer shall add the ICD-10 CM code provided in the link effective 1/1/2021 to the list of ICD-10-CM codes that are covered by Medicare for the Fecal Occult Blood Test (190.34) NCD.									Fu Associates
12468.26	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
12468.27	The SSMs shall install the edit module after testing and distribute it to the contractors as part					X	X			

Number	Requirement	Responsibility								
		A/B MAC		DME	Share	d-Syste	Other			
		Α	В	ННН		FISS	MCS	VMS	CWF	
					MAC					
	of their routine release.									
12468.28	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							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Re	spoi	ısibility	7	
			A/ M/		DME MAC	CEDI
		A	В	ННН		
12468.29	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the "MLN Connects" listserv to get MLN content notifications. You don't need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.	X	X			

IV. SUPPORTING INFORMATION

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

[&]quot;Should" denotes a recommendation.

X-Ref	Recommendations or other supporting information:
Requirement	
Number	

Section B: All other recommendations and supporting information: $\ensuremath{\mathrm{N/A}}$

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