CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 12817	Date: August 29, 2024
	Change Request 13785

SUBJECT: Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2025

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to announce the changes that will be included in the January 2025 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, 2025 - Unless noted differently in requirements.

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

IMPLEMENTATION DATE: January 6, 2025

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

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II. GENERAL INFORMATION

A. Background:

The purpose of this Change Request (CR) is to announce the changes that will be included in the January 2025 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 2025. Please access the link below for the NCD spreadsheet included with this change request:

https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/January-2025.zip

III. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A	A/B MAC		DME	Share	d-Syste	tainers	Other	
		Α				FISS	MCS	VMS	CWF	
					MAC					
13785.1	The module developer									Fu
	shall add ICD-10-CM									Associates
	codes provided in the									

Number	Requirement	Responsibility								
		A	/B 1	MAC	DME	Share	d-Syste	m Main	tainers	Other
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
	link effective 10/1/2024 to the list of ICD-10- CM codes that are denied by Medicare for the Urine Culture, Bacterial (190.12) NCD.									
13785.2	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 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
13785.3	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 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
13785.3.1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 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
13785.4	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024									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	
	to the list of ICD-10-CM codes that are not medically necessary for the Blood Counts (190.15) NCD.									
13785.4.1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are denied by Medicare for the Blood Counts (190.15) NCD.									Fu Associates
13785.5	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are covered by Medicare for the Partial Thromboplastin Time (PTT) (190.16) NCD.									Fu Associates
13785.5.1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are denied by Medicare for the Partial Thromboplastin Time (PTT) (190.16) NCD.									Fu Associates
13785.6	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are covered by Medicare for the Prothrombin Time (PT) (190.17) NCD.									Fu Associates
13785.6.1	The module developer shall add ICD-10 CM codes provided in the									Fu Associates

Number	Requirement	Responsibility								
		Α		MAC	DME		d-Syste			Other
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
	link effective 10/1/2024 to the list of ICD-10- CM codes that are denied by Medicare for the Prothrombin Time (PT) (190.17) NCD.									
13785.7	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are covered by Medicare for the Serum Iron Studies (190.18) NCD.									Fu Associates
13785.7.1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are denied by Medicare for the Serum Iron Studies (190.18) NCD.									Fu Associates
13785.8	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are denied by Medicare for the Collagen Crosslinks, Any Method (190.19) NCD.									Fu Associates
13785.9	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are covered by Medicare for the Blood Glucose Testing (190.20A) NCD.									Fu Associates
13785.9.1	The module developer shall add ICD-10 CM									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	
	codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are denied by Medicare for the Blood Glucose Testing (190.20A) NCD.									
13785.10	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are covered by Medicare for the Blood Glucose Testing (190.20B) NCD.									Fu Associates
13785.10.1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are denied by Medicare for the Blood Glucose Testing (190.20B) NCD.									Fu Associates
13785.11	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are covered by Medicare for the Glycated Hemoglobin/Glycated Protein (190.21A) NCD.									Fu Associates
13785.11.1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are denied by Medicare for the Glycated Hemoglobin/Glycated									Fu Associates

Number	Requirement	Re								
		A/B MAC			DME	Share	d-Syste	m Main	tainers	Other
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
	Protein (190.21A) NCD.									
13785.12	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are covered by Medicare for the Glycated Hemoglobin/Glycated Protein (190.21B) NCD.									Fu Associates
13785.12.1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are denied by Medicare for the Glycated Hemoglobin/Glycated Protein (190.21B) NCD.									Fu Associates
13785.13	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are covered by Medicare for the Thyroid Testing (190.22) NCD.									Fu Associates
13785.13.1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are denied by Medicare for the Thyroid Testing (190.22) NCD.									Fu Associates
13785.14	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are covered by Medicare for									Fu Associates

Number	Requirement	Responsibility								
		Α		MAC	DME		d-Syste		l .	Other
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
	the Lipids Testing (190.23A) NCD.									
13785.14.1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are denied by Medicare for the Lipids Testing (190.23A) NCD.									Fu Associates
13785.15	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are covered by Medicare for the Lipids Testing (190.23B) NCD.									Fu Associates
13785.15.1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are denied by Medicare for the Lipids Testing (190.23B) NCD.									Fu Associates
13785.16	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are denied by Medicare for the Digoxin Therapeutic Drug Assay (190.24) NCD.									Fu Associates
13785.17	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are covered by Medicare for									Fu Associates

Number	Requirement	Responsibility								
		Α	A/B I	MAC	DME	Share	d-Syste	m Main	tainers	Other
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
	the Alpha-fetoprotein (190.25) NCD.									
13785.17.1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are denied by Medicare for the Alpha-fetoprotein (190.25) NCD.									Fu Associates
13785.18	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are denied by Medicare for the Carcinoembryonic Antigen (190.26) NCD.									Fu Associates
13785.19	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are denied by Medicare for the Human Chorionic Gonadotropin (190.27) NCD.									Fu Associates
13785.20	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 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
13785.21	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are									Fu Associates

Number	Requirement	Responsibility								
		Α	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 Tumor Antigen by Immunoassay CA 15- 3/CA 27.29 (190.29) NCD.									
13785.21.1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 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
13785.22	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 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
13785.23	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are denied by Medicare for the Prostate Specific Antigen (190.31) NCD.									Fu Associates
13785.24	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 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								
				MAC	DME		I	m Main		Other
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
13785.24.1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are denied by Medicare for the Gamma Glutamyl Transferase (190.32) NCD.				,,,,,,,					Fu Associates
13785.25	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 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
13785.26	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are covered by Medicare for the Fecal Occult Blood Test (190.34) NCD.									Fu Associates
13785.26.1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2024 to the list of ICD-10-CM codes that are denied by Medicare for the Fecal Occult Blood Test (190.34) NCD.									Fu Associates
13785.27	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

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers			Other	
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
13785.28	The SSMs shall install the edit module after testing and distribute it to the contractors as part of their routine release.					X	X			
13785.29	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							

IV. PROVIDER EDUCATION TABLE

Number	Requirement	Re	spoi	ısibility	,	
			A/ M/		DME MAC	CEDI
		A	В	ННН		
13785.30	Medicare Learning Network® (MLN): CMS will develop and release national provider education content and market it through the MLN Connects® newsletter shortly after we issue the CR. MACs shall link to relevant information on your website and follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 for distributing the newsletter to providers. When you follow this manual section, you don't need to separately track and report MLN content releases. You may supplement with your local educational content after we release the newsletter.	X	X			

V. 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	

VI. CONTACTS

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

VII. 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