CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11170	Date: December 22, 2021
	Change Request 12575

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

I. SUMMARY OF CHANGES: This Change Request (CR) announces the changes that will be included in the April 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: April 1, 2022 - Unless noted differently in requirements.

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

IMPLEMENTATION DATE: April 4, 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: 11170 Date: December 22, 2021 Change Request: 12575

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

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

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

IMPLEMENTATION DATE: April 4, 2022

I. GENERAL INFORMATION

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

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

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Re	espo	nsil	bilit	y				
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12575.1	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2021 to the list of									
	ICD-10-CM codes that are denied by Medicare for the									
	Urine Culture, Bacterial (190.12) NCD.									
12575.1.1	The module developer shall delete ICD-10 CM codes									Fu Associates
	provided in the link effective 9/30/2021 from the list									
	of ICD-10-CM codes that are denied by Medicare for									

Number	Requirement	Re	espo	nsil	bilit	.y				
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	the Urine Culture, Bacterial (190.12) NCD.					ט				
12575.2	The module developer shall add ICD-10 CM codes									Fu Associates
12373.2	provided in the link effective 10/1/2021 to the list of									1 d 7 issociates
	ICD-10-CM codes that are denied by Medicare for the									
	Human Immunodeficiency Virus (HIV)Testing (Prognosis Including Monitoring) (190.13) NCD.									
	(Freghesis merading Momenting) (Free 1)									
12575.2.1	The module developer shall delete ICD-10 CM codes									Fu Associates
	provided in the link effective 9/30/2021 from 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.									
12575.3	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2021 to the list of									
	ICD-10-CM codes that are denied by Medicare for the Human Immunodeficiency Virus (HIV) Testing									
	(Diagnosis) (190.14) NCD.									
10575.0.1										T .
12575.3.1	The module developer shall delete ICD-10 CM codes provided in the link effective 9/30/2021 from the list									Fu Associates
	of ICD-10-CM codes that are denied by Medicare for									
	the Human Immunodeficiency Virus (HIV) Testing									
	(Diagnosis) (190.14) NCD.									
12575.4	The module developer shall add the ICD-10 CM code									Fu Associates
	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.									
10575 1 1										·
12575.4.1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2021 to the list of									Fu Associates
	ICD-10-CM codes that are denied by Medicare for the									
	Blood Counts (190.15) NCD.									
12575.4.2	The module developer shall delete ICD-10 CM codes									Fu Associates
	provided in the link effective 9/30/2021 from the list									
	of ICD-10-CM codes that are denied by Medicare for									
	the Blood Counts (190.15) NCD.									
12575.5	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2021 to the list of ICD-10-CM codes that are denied by Medicare for the									
	Partial Thromboplastin Time (PTT) (190.16) NCD.									

Number	Requirement	Re	espo	nsil	bilit	V				
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12575.5.1	The module developer shall delete ICD-10 CM codes provided in the link effective 9/30/2021 from the list of ICD-10-CM codes that are denied by Medicare for the Partial Thromboplastin Time (PTT) (190.16) NCD.									Fu Associates
12575.6	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 denied by Medicare for the Prothrombin Time (PT) (190.17) NCD.									Fu Associates
12575.6.1	The module developer shall delete ICD-10 CM codes provided in the link effective 9/30/2021 from the list of ICD-10-CM codes that are denied by Medicare for the Prothrombin Time (PT) (190.17) NCD.									Fu Associates
12575.7	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 denied by Medicare for the Serum Iron Studies (190.18) NCD.									Fu Associates
12575.7.1	The module developer shall delete ICD-10 CM cods provided in the link effective 9/30/2021 from the list of ICD-10-CM codes that are denied by Medicare for the Serum Iron Studies (190.18) NCD.									Fu Associates
12575.8	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 denied by Medicare for the Collagen Crosslinks, Any Method (190.19) NCD.									Fu Associates
12575.8.1	The module developer shall delete ICD-10 CM codes provided in the link effective 9/30/2021 from the list of ICD-10-CM codes that are denied by Medicare for the Collagen Crosslinks, Any Method (190.19) NCD.									Fu Associates
12575.9	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 Blood Glucose Testing (190.20A) NCD.									Fu Associates
12575.9.1	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 denied by Medicare for the Blood Glucose Testing (190.20A) NCD.									Fu Associates

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12575.9.2	The module developer shall delete ICD-10 CM codes					S				Fu Associates
	provided in the link effective 9/30/2021 from the list									
	of ICD-10-CM codes that are denied by Medicare for the Blood Glucose Testing (190.20A) NCD.									
	the Blood Glucose Testing (190.20A) Neb.									
12575.10	The module developer shall add the ICD-10 CM code									Fu Associates
	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.									
12575 10	The medule development of all of LOD 10 CM 1									Ess A second
12575.10. 1	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2021 to the list of									Fu Associates
	ICD-10-CM codes that are denied by Medicare for the									
	Blood Glucose Testing (190.20B) NCD.									
12575.10.	The module developer shall delete ICD-10 CM codes									Fu Associates
2	provided in the link effective 9/30/2021 from the list									
	of ICD-10-CM codes that are denied by Medicare for the Blood Glucose Testing (190.20B) NCD.									
	the Blood Glacose Testing (170.20B) 110B.									
12575.11	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2021 to the list of ICD-10-CM codes that are denied by Medicare for the									
	Glycated Hemoglobin/Glycated Protein (190.21)									
	NCD.									
12575.11.	The module developer shall delete ICD-10 CM codes									Fu Associates
1	provided in the link effective 9/30/2021 from the list									
	of ICD-10-CM codes that are denied by Medicare for the Glycated Hemoglobin/Glycated Protein (190.21)									
	NCD.									
12575.12	The module developer shall add the ICD-10 CM code									Fu Associates
12373.12	provided in the link effective 10/1/2021 to the list of									1 d / 1330clates
	ICD-10-CM codes that are covered by Medicare for									
	the Thyroid Testing (190.22) NCD.									
12575.12.	The module developer shall add ICD-10 CM codes									Fu Associates
1	provided in the link effective 10/1/2021 to the list of ICD-10-CM codes that are denied by Medicare for the									
	Thyroid Testing (190.22) NCD.									
10575 10	•									F
12575.12.	The module developer shall delete ICD-10 CM codes provided in the link effective 9/30/2021 from the list									Fu Associates
-	of ICD-10-CM codes that are denied by Medicare for									
	the Thyroid Testing (190.22) NCD.									

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12575.13	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2021 to the list of									
	ICD-10-CM codes that are denied by Medicare for the									
	Lipids Testing (190.23A) NCD.									
12575.13.	The medule developes shall delete ICD 10 CM as dec									Fu Associates
12373.13.	The module developer shall delete ICD-10 CM codes provided in the link effective 9/30/2021 from the list									ru Associates
1	of ICD-10-CM codes that are denied by Medicare for									
	the Lipids Testing (190.23A) NCD.									
	<u></u>									
12575.14	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2021 to the list of									
	ICD-10-CM codes that are denied by Medicare for the									
	Lipids Testing (190.23B) NCD.									
12575.14.	The weathle developed the Halate ICD 10 CM as dec									En Associates
125/5.14.	The module developer shall delete ICD-10 CM codes provided in the link effective 9/30/2021 from the list									Fu Associates
1	of ICD-10-CM codes that are denied by Medicare for									
	the Lipids Testing (190.23B) NCD.									
	the Lipids Testing (190.23B) TVSB.									
12575.15	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2021 to the list of									
	ICD-10-CM codes that are denied by Medicare for the									
	Digoxin Therapeutic Drug Assay (190.24) NCD.									
12575.15.	The weathle developed the Halate ICD 10 CM as dec									Fu Associates
123/3.13.	The module developer shall delete ICD-10 CM codes provided in the link effective 9/30/2021 from the list									ru Associates
1	of ICD-10-CM codes that are denied by Medicare for									
	the Digoxin Therapeutic Drug Assay (190.24) NCD.									
12575.16	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2021 to the list of									
	ICD-10-CM codes that are denied by Medicare for the									
	Alpha-fetoprotein (190.25) NCD.									
12575.16.	The module developer shall delete ICD-10 CM codes									Fu Associates
12373.10.	provided in the link effective 9/30/2021 from the list									ru Associates
1	of ICD-10-CM codes that are denied by Medicare for									
	the Alpha-fetoprotein (190.25) NCD.									
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12575.17	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2021 to the list of									
	ICD-10-CM codes that are denied by Medicare for the									
	Carcinoembryonic Antigen (190.26) NCD.									
12575.17.	The module developer shall delete ICD 10 CM and an									Fu Associates
123/3.1/.	The module developer shall delete ICD-10 CM codes provided in the link effective 9/30/2021 from the list									ru Associates
1	provided in the link effective 3/30/2021 from the list						<u> </u>			

Number	Requirement	Re	espo	nsil	bilit	V				
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	of ICD-10-CM codes that are denied by Medicare for the Carcinoembryonic Antigen (190.26) NCD.									
12575.18	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 denied by Medicare for the Human Chorionic Gonadotropin (190.27) NCD.									Fu Associates
12575.18.	The module developer shall delete ICD-10 CM codes provided in the link effective 9/30/2021 from the list of ICD-10-CM codes that are denied by Medicare for the Human Chorionic Gonadotropin (190.27) NCD.									Fu Associates
12575.19	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 denied by Medicare for the Tumor Antigen by Immunoassay CA 125 (190.28) NCD.									Fu Associates
12575.19.	The module developer shall delete ICD-10 CM codes provided in the link effective 9/30/2021 from 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
12575.20	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 denied by Medicare for the Tumor Antigen by Immunoassay CA 15-3/CA 27.29 (190.29) NCD.									Fu Associates
12575.20. 1	The module developer shall delete ICD-10 CM codes provided in the link effective 9/30/2021 from 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
12575.21	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 denied by Medicare for the Tumor Antigen by Immunoassay CA 19-9 (190.30) NCD.									Fu Associates
12575.21. 1	The module developer shall delete ICD-10 CM codes provided in the link effective 9/30/2021 from the list of ICD-10-CM codes that are denied by Medicare for the Tumor Antigen by Immunoassay CA 19-9									Fu Associates

Number	Requirement	Re	espo	nsil	bilit	.y				
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	(190.30) NCD.									
10575 00	The second of th									To A sussistan
12575.22	The module developer shall add ICD-10 CM codes provided in the link effective 10/1/2021 to the list of									Fu Associates
	ICD-10-CM codes that are denied by Medicare for the									
	Prostate Specific Antigen (190.31) NCD.									
10.555.00										
12575.22.	The module developer shall delete ICD-10 CM codes									Fu Associates
1	provided in the link effective 9/30/2021 from the list of ICD-10-CM codes that are denied by Medicare for									
	the Prostate Specific Antigen (190.31) NCD.									
	18 (
12575.23	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2021 to the list of									
	ICD-10-CM codes that are denied by Medicare for the									
	Gamma Glutamyl Transferase (190.32) NCD.									
12575.23.	The module developer shall delete ICD-10 CM codes									Fu Associates
1	provided in the link effective 9/30/2021 from the list									
	of ICD-10-CM codes that are denied by Medicare for									
	the Gamma Glutamyl Transferase (190.32) NCD.									
12575.24	The module developer shall add ICD-10 CM codes									Fu Associates
	provided in the link effective 10/1/2021 to the list of									
	ICD-10-CM codes that are denied by Medicare for the									
	Hepatitis Panel/Acute Hepatitis Panel (190.33) NCD.									
12575.24.	The module developer shall delete ICD-10 CM codes									Fu Associates
1	provided in the link effective 9/30/2021 from the list									
	of ICD-10-CM codes that are denied by Medicare for									
	the Hepatitis Panel/Acute Hepatitis Panel (190.33)									
	NCD.									
12575.25	The module developer shall add the ICD-10 CM code									Fu Associates
	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.									
12575.25.	The module developer shall add ICD-10 CM codes									Fu Associates
12373.23.	provided in the link effective 10/1/2021 to the list of									1 4 1 1550014105
	ICD-10-CM codes that are denied by Medicare for the									
	Fecal Occult Blood Test (190.34) NCD.									
12575.25.	The module developer shall delete ICD-10 CM codes									Fu Associates
2	provided in the link effective 9/30/2021 from the list									1 a Associates
	of ICD-10-CM codes that are denied by Medicare for		L						L	
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Number	Requirement	Re	espo	nsil	bilit	V				
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	the Fecal Occult Blood Test (190.34) NCD.									
12575.26	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
12575.27	The SSMs shall install the edit module after testing and distribute it to the contractors as part of their routine release.					X	X			
12575.28	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	spo	nsib	ility	
			A/B MA(D M E	C E D
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12575.29	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: N/A

V. CONTACTS

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