

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-20 One-Time Notification	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11461	Date: June 21, 2022
	Change Request 12483

Transmittal 11055, dated October 21, 2021, is being rescinded and replaced by Transmittal 11461, dated, June 21, 2022 to revise BR 12483.1 and corresponding spreadsheet to align with changes made in previous CR 12124 and later CR 12705. All other information remains the same.

SUBJECT: National Coverage Determination (NCD) 90.2, Next Generation Sequencing (NGS)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to provide updates to the International Classification of Diseases (ICD) -10 diagnosis codes for covered clinical diagnostic lab test related to the Next Generation Sequencing (NGS) policy.

EFFECTIVE DATE: July 1, 2020

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

IMPLEMENTATION DATE: November 23, 2021

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:

One Time Notification

Attachment - One-Time Notification

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SUBJECT: National Coverage Determination (NCD) 90.2, Next Generation Sequencing (NGS)

EFFECTIVE DATE: July 1, 2020

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IMPLEMENTATION DATE: November 23, 2021

I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) reviewed the evidence for laboratory diagnostic tests using NGS in patients with cancer, and determined that such tests with analytical and clinical validity, and clinical utility, could also improve health outcomes for Medicare beneficiaries with advanced cancer. Therefore, CMS shall cover certain diagnostic laboratory tests using NGS under the conditions specified below.

B. Policy: CMS released a number of Change Requests (CRs) for NCD 90.2, NGS. Please see spreadsheet for CR history. CR 12483 provides updated ICD-10 diagnosis codes for covered clinical diagnostic lab test MyChoice CDx™, effective July 1, 2020, as well as updated ICD-10 diagnosis codes resulting from the October 1, 2021, annual ICD-10 update.

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	
12483.1	Effective for claims with dates of service on or after July 1, 2020, for MyChoice CDx™, Current Procedural Terminology (CPT) 0172U, contractors shall: - Add ICD-10 diagnosis C48.0, C48.1, C48.2, C48.8, C56.9, C57.00, C57.01, C57.02. - End-date ICD-10 diagnosis D07.39, D27.0, D27.1, D39.11, D39.12. Effective for claims with dates of service on and after October	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	1, 2021, contractors shall: - Add ICD-10 diagnosis C56.3, for CPT 0037U, 0172U, 0239U, 0242U. - Add ICD-10 diagnosis C79.63 for CPT 0172U. See spreadsheet.									
12483.2	Contractors shall adjust claims brought to their attention that were processed in error prior to the implementation date of this CR.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	None					

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): Wanda Belle, 4107867491 or wanda.belle@cms.hhs.gov (Coverage and Analysis Group) , Patricia Brocato-Simons, 4107860261 or Patricia.BrocatoSimons@cms.hhs.gov (Coverage and Analysis Group)

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

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

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