Article - Billing and Coding: MolDX: Targeted and Comprehensive Genomic Profile Next-Generation Sequencing Testing in Cancer (A56518)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
Noridian Healthcare Solutions, LLC	A and B MAC	02101 - MAC A	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02102 - MAC B	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02201 - MAC A	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02202 - MAC B	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02301 - MAC A	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02302 - MAC B	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02401 - MAC A	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	02402 - MAC B	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	03101 - MAC A	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03102 - MAC B	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03201 - MAC A	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03202 - MAC B	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03301 - MAC A	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03302 - MAC B	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03401 - MAC A	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03402 - MAC B	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03501 - MAC A	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03502 - MAC B	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03601 - MAC A	J - F	Wyoming
Noridian Healthcare Solutions, LLC	A and B MAC	03602 - MAC B	J - F	Wyoming

Article Information

General Information

Article ID
A56518

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

Article Title
Billing and Coding: MolDX: Targeted and Comprehensive Genomic Profile Next-Generation Sequencing Testing in Cancer

Article Type
Billing and Coding

Original Effective Date
05/27/2019

Revision Effective Date
03/16/2022

Revision Ending Date
N/A

Retirement Date
N/A

CMS National Coverage Policy

N/A

Article Guidance

Article Text

Next Generation Sequencing (NGS)

NGS allows identification of somatic and/or germline alterations in multiple genes simultaneously. This guideline focuses on Targeted and Comprehensive Genomic Profile testing for somatic variant detection using tumor tissue only-based panels for cancer.

Definitions:

Targeted Tumor Panels

Targeted Next-Generation Sequencing (NGS) panels are hereby defined as tests that identify somatic alterations known to occur in certain regions (i.e., **'hotspots'**) within specific genes of interest for cancer management (i.e., diagnosis, selection of molecularly targeted therapies, prognosis in a context where prognostic classification is essential for treatment selection). Generally, these NGS panels can detect single nucleotide variants (SNVs) and small insertions or deletions (INDELs) within these regions. These alterations typically represent response or lack of response to corresponding targeted cancer therapies. The hotspot test should include relevant regions in the genes required for companion diagnostic testing and/or known to be necessary for proper patient management.

Comprehensive Genomic Profile (CGP) Testing

CGP refers to NGS-based molecular assays that provide additional insight beyond individual gene hotspots; these assays seek to describe the genomic makeup of a tumor and can help identify underlying mechanisms of disease to guide clinical decision making. These tests include not only mutations in individual relevant genes, but also patterns of mutations across related genes in established cancer pathways and often include an assessment of overall mutational burden. These tests typically involve sequencing of entire exonic regions of genes of interest (within a comprehensive gene panel or whole exome sequencing) and may also include selected intronic regions. CGP can detect multiple types of molecular alterations (i.e., SNVs, small and large INDELs, copy number alterations (CNAs), structural variants (SVs), and splice-site variants) in a single assay. Patterns of mutations seen across multiple genes may be used to infer clinically relevant etiologies, such as DNA mismatch repair deficiency and microsatellite instability, and total mutational load/burden (TMB) may be determined. CGP testing may also include RNA sequencing to detect structural variations, such as translocations or large deletions, and to detect functional splicing mutations. CGP is not defined as a targeted panel by MolDX.

CPT® coding Instructions

Targeted Panels

To bill for targeted NGS gene panel services for somatic variant detection, review CPT® codes 81445 and 81450. The units of service (UOS) for an NGS gene panel is one (UOS=1). Providers must also provide the approved DEX Z-Code identifier for the test.

Effective July 1, 2017, laboratories with 2 to 4 genes on their targeted NGS panel should use CPT® 81479 and one (1) UOS along with their test identifier (DEX Z-Code™) to represent this service on their claims.

CGP

As CGP testing is not defined as a targeted panel by MolDX, and it is a test not currently satisfactorily described by any existing CPT code. Therefore, to report a CGP service, test providers should use CPT® code 81479 at this time, in addition to the approved DEX Z-Code™ for the test. Coverage of CGP is limited to one test per surgical specimen and precludes the use of any other molecular testing on that specimen.

For NGS-based tests that do not fit under the above definitions of "targeted" or "Comprehensive" panels, billing with the "Not Otherwise Classified" (NOC) code 81479 along with the approved DEX Z-Code™ identifier is appropriate.

Tier 1 and/or Tier 2 individual biomarker CPT codes should not be used for a single gene or any combination of genes when testing is performed as part of a NGS or other multiplexing technology panel.

Refer to Billing and Coding: MolDX: Next-Generation Sequencing for Solid Tumors A57905 for CPT/HCPCS codes and ICD-10 codes relevant for solid tumors.

Refer to Billing and Coding: MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies A57892 for CPT/HCPCS codes and ICD-10 codes relevant for myeloid malignancies.

Coding Information

CPT/HCPCS Codes

Group 1 Paragraph:

N/A

Group 1 Codes:

N/A

CPT/HCPCS Modifiers

Group 1 Paragraph:

N/A

Group 1 Codes:

N/A

ICD-10-CM Codes that Support Medical Necessity

Group 1 Paragraph:

N/A

Group 1 Codes:

N/A

ICD-10-CM Codes that DO NOT Support Medical Necessity

Group 1 Paragraph:

N/A

Group 1 Codes:

N/A

ICD-10-PCS Codes

Group 1 Paragraph:

N/A

Group 1 Codes:

N/A

Additional ICD-10 Information

N/A

Bill Type Codes

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

N/A

Revenue Codes

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the article, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the article should be assumed to apply equally to all Revenue Codes.

N/A

Other Coding Information

Group 1 Paragraph:

N/A

Group 1 Codes:

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
03/16/2022	R6	Under **Article Text** added verbiage and hyperlinks for "Refer to Billing and Coding: MolDX: Next-Generation Sequencing for Solid Tumors for CPT/HCPCS codes and ICD-10 codes relevant for solid tumors. Refer to Billing and Coding: MolDX: Next-Generation Sequencing Lab-Developed Test for CPT/HCPCS codes and ICD-10 codes relevant for myeloid malignancies". Under **CPT/HCPCS Codes Group 1: Paragraph** deleted the verbiage. Under **CPT/HCPCS Codes Group 1: Codes** deleted all CPT/HCPCS codes listed. Under **CPT/HCPCS Group 2: Paragraph** deleted the verbiage. Under

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		CPT/HCPCS Codes Group 2: Codes deleted all CPT/HCPCS codes listed. Under **ICD-10 Codes that Support Medical Necessity Group 1: Paragraph** deleted the verbiage. Under **ICD-10 Codes that Support Medical Necessity Group 1: Codes** deleted all ICD-10 codes listed. Under **ICD-10 Codes that Support Medical Necessity Group 2: Paragraph** deleted the verbiage. Under **ICD-10 Codes that Support Medical Necessity Group 2: Codes** deleted all ICD-10 codes listed.
01/01/2022	R5	Under **CPT/HCPCS Codes Group 2: Codes** the description was revised for 0244U. This revision is due to the 2022 Annual CPT/HCPCS Code Update and is effective on January 1, 2022. Under **ICD-10 Codes that Support Medical Necessity Group 1: Codes** added D46.4, D47.9, D72.829, and D75.9. Under **ICD-10 Codes that Support Medical Necessity Group 2: Codes** added: C00.2, C00.5, C00.6, C00.9, C02.3, C02.9, C03.9, C04.9, C05.9, C06.80, C06.9, C08.9, C09.9, C10.9, C11.9, C13.9, C14.0, C15.9, C16.5, C16.6, C16.9, C17.9, C18.9, C21.0, C22.8, C24.9, C25.9, C26.0, C31.9, C32.9, C34.00, C34.10, C34.30, C34.80, C34.90, C34.91, C34.92, C38.3, C39.0, C39.9, C40.00, C40.10, C40.20, C40.30, C40.80, C40.90, C40.91, C40.92, C41.9, C43.10, C43.20, C43.30, C43.60, C43.70, C43.9, C4A.10, C4A.20, C4A.30, C4A.60, C4A.70, C4A.9, C44.00, C44.101, C44.1021, C44.1022, C44.1091, C44.1092, C44.111, C44.121, C44.191, C44.201, C44.202, C44.209, C44.211, C44.221, C44.291, C44.300, C44.301, C44.309, C44.310, C44.320, C44.390, C44.40, C44.500, C44.501, C44.509, C44.601, C44.602, C44.609, C44.611, C44.621, C44.691, C44.701, C44.702, C44.709, C44.711, C44.721, C44.791, C44.80, C44.90, C44.91, C44.92, C44.99, C45.9, C47.10, C47.20, C47.6, C47.9, C48.2, C49.10, C49.20, C49.6, C49.9, C49.A0, C50.019, C50.029, C50.119, C50.129, C50.219, C50.229, C50.319, C50.329, C50.419, C50.429, C50.519, C50.529, C50.619, C50.629, C50.819, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C51.9, C53.9, C54.9, C55, C56.9, C57.00, C57.10, C57.20, C57.4, C57.9, C60.9, C62.00, C62.10, C62.90, C62.91, C62.92, C63.00, C63.10, C63.9, C64.9, C65.9, C66.9, C67.9, C68.9, C69.00, C69.10, C69.20, C69.30, C69.40, C69.50, C69.60, C69.80, C69.90, C69.91, C69.92, C70.9, C71.9, C72.20, C72.30, C72.40, C72.50, C72.9, C74.00, C74.10, C74.90, C74.91, C74.92, C75.8, C75.9 C7A.00, C7A.019, C7A.029, C7A.094, C7A.095, C7A.096, C76.40, C76.50, C80.0, and C80.1. The deletion of these codes with Revision 11 was done in error and is retroactive effective for dates of service on or after 06/24/2021.
11/08/2021	R4	11/08/2021: Under ICD-10 Codes that Support Medical Necessity Group I: Codes deleted D46.9 10/01/2021: Under CPT/HCPCS Codes Group 2: Codes added 0250U. This revision is due to the Q3 2021 CPT/HCPCS Code Update and is effective for dates of service on or after 7/1/2021. Under ICD-10 Codes that Support Medical Necessity Group 1: Codes added D75.838.

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		Under ICD-10 Codes that Support Medical Necessity Group 2: Codes added C56.3. This revision is due to the Annual ICD-10 Update and will become effective on 10/1/2021.
06/24/2021	R3	Under **CPT/HCPCS Codes Group 2: Codes** added 0244U. This revision is due to the Q2 2021 CPT/HCPCS Code Update and is effective for dates of service on or after 4/1/2021. Under **Article Text** subsection **Targeted Panels** revised second paragraph to read "Effective July 1, 2017, laboratories with 2 to 4 genes on their targeted NGS panel should use CPT 81479 and one (1) UOS along with their test identifier (DEX Z-Code™) to represent this service on their claims" and moved second sentence to end of article text. Under **ICD-10 Codes that Support Medical Necessity Group 1: Codes** deleted D46.4, D47.9, D72.829, and D75.9. Under **ICD-10 Codes that Support Medical Necessity Group 2: Codes** deleted C00.2, C00.5, C00.6, C00.9, C02.3, C02.9, C03.9, C04.9, C05.9, C06.80, C06.9, C08.9, C09.9, C10.9, C11.9, C13.9, C14.0, C15.9, C16.5, C16.6, C16.9, C17.9, C18.9, C21.0, C22.8, C24.9, C25.9, C26.0, C31.9, C32.9, C34.00, C34.10, C34.30, C34.80, C34.90, C34.91, C34.92, C38.3, C39.0, C39.9, C40.00, C40.10, C40.20, C40.30, C40.80, C40.90, C40.91, C40.92, C41.9, C43.10, C43.20, C43.30, C43.60, C43.70, C43.9, C4A.10, C4A.20, C4A.30, C4A.60, C4A.70, C4A.9, C44.00, C44.101, C44.1021, C44.1022, C44.1091, C44.1092, C44.111, C44.121, C44.191, C44.201, C44.202, C44.209, C44.211, C44.221, C44.291, C44.300, C44.301, C44.309, C44.310, C44.320, C44.390, C44.40, C44.500, C44.501, C44.509, C44.601, C44.602, C44.609, C44.611, C44.621, C44.691, C44.701, C44.702, C44.709, C44.711, C44.721, C44.791, C44.80, C44.90, C44.91, C44.92, C44.99, C45.9, C47.10, C47.20, C47.6, C47.9, C48.2, C49.10, C49.20, C49.6, C49.9, C49.A0, C50.019, C50.029, C50.119, C50.129, C50.219, C50.229, C50.319, C50.329, C50.419, C50.429, C50.519, C50.529, C50.619, C50.629, C50.819, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C51.9, C53.9, C54.9, C55, C56.9, C57.00, C57.10, C57.20, C57.4, C57.9, C60.9, C62.00, C62.10, C62.90, C62.91, C62.92, C63.00, C63.10, C63.9, C64.9, C65.9, C66.9, C67.9, C68.9, C69.00, C69.10, C69.20, C69.30, C69.40, C69.50, C69.60, C69.80, C69.90, C69.91, C69.92, C70.9, C71.9, C72.20, C72.30, C72.40, C72.50, C72.9, C74.00, C74.10, C74.90, C74.91, C74.92, C75.8, C75.9 C7A.00, C7A.019, C7A.029, C7A.094, C7A.095, C7A.096, C76.40, C76.50, C80.0, and C80.1.
12/01/2019	R2	As required by CR 10901, article is converted to a formal billing and coding type article. Under **Article Title** changed the title from "MolDX: Targeted and Comprehensive Genomic Profile Next-Generation Sequencing Testing in Cancer" to "Billing and Coding: MolDX: Targeted and Comprehensive Genomic Profile Next-Generation Sequencing Testing in Cancer". Formatting, punctuation and typographical errors were corrected throughout the article. There is no change in coverage.
05/27/2019	R1	HCPCS coding was divided into two paragraphs to provide greater clarity in billing.

Associated Documents

Related Local Coverage Documents

LCDs

L38121 - MolDX: Next-Generation Sequencing for Solid Tumors

L38125 - MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies

Related National Coverage Documents

N/A

Statutory Requirements URLs

N/A

Rules and Regulations URLs

N/A

CMS Manual Explanations URLs

N/A

Other URLs

N/A

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
03/22/2022	03/16/2022 - N/A	Currently in Effect (This Version)
01/18/2022	01/01/2022 - 03/15/2022	Superseded
11/30/2021	11/08/2021 - 12/31/2021	Superseded
06/17/2021	06/24/2021 - 11/07/2021	Superseded
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.		

Keywords

N/A