LCD Reference Article	Billing and Coding Article

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

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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
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Noridian Healthcare Solutions, LLC	A and B MAC	02402 - MAC B	J - F	Washington
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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 Testing in Cancer

Article Type
Billing and Coding

Original Effective Date
05/27/2019

Revision Effective Date
03/21/2024

Revision Ending Date
N/A

Retirement Date
N/A

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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-based panels for cancer that may be performed by NGS.

Refer to MolDX: Defining panel services in MolDX A59687 for further guidance on the distinction between single analyte and panel tests.

Definitions:

Targeted Tumor Panels

Targeted tumor 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 panels are limited to specific variant types at defined sites, such as single nucleotide variants (SNVs), small insertions or deletions (INDELs), single site copy number variants, or gene fusions. These alterations typically represent response or lack of response to corresponding targeted cancer therapies. The hotspot test should include relevant targets required for companion diagnostic testing and/or known to be necessary for proper patient management.

Comprehensive Genomic Profile (CGP) Testing

CGP testing 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 select intronic regions. CGP tests can detect multiple types of molecular alterations (i.e., SNVs, small and large INDELs, copy number variants (CNVs), 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 (MSI), total mutational load/burden (TMB) and chromosome abnormalities such as loss of heterozygosity (LOH). CGP testing may also include RNA sequencing to detect structural variations, such as translocations or large deletions, and to detect functional splicing mutations. CGP testing is not defined as a targeted panel by MolDX. CGP tests are expected to yield information of clinical relevance beyond a targeted panel, for example, to identify relevant clinical trials for patient management or identify possible therapeutic interventions for off-label use. It is expected that a CGP will identify all clinically relevant information attainable for the type of service performed.

CPT® coding Instructions

Targeted Tumor Panels

To bill for DNA-based panels that measure specific SNVs, INDELs, CNVs or rearrangements, review CPT codes 81445 and 81450. If a DNA-based targeted panel meeting the coverage requirements is used, and MSI is also performed, 81457 can be billed. If a DNA-based targeted test meeting coverage requirements is performed that includes MSI and CNVs, 81458 can be billed.

81449 or 81451 for RNA-based targeted testing may also be billed for the same specimen that received a DNA-based NGS test if compliant with the language of A57503, is non-duplicative, and performed serially to DNA testing as a separate service (with a separate order and report). If only RNA-based testing is reasonable and necessary, 81449 or 81451 may be billed alone if policy requirements are met. If two targeted panels (one for DNA and the other for RNA) are always performed together and meet policy criteria, 81479 should be used for such a service to reduce claims processing errors as this would constitute one service.

The unit 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

CPT code 81459, based on the inclusion of the comprehensive test components addressed in the definition above, is considered a CGP test by this contractor and may be billed when all stated components of the service have satisfied technical assessment requirements. Because this code includes both DNA-only and DNA/RNA combined services in its description, it is assumed that services that include DNA/RNA combined testing add no additional relevant genomic information beyond that provided by a DNA-only test. For CGP tests that include the use of RNA to interrogate relevant genomic information beyond that captured with DNA-based testing, billing with CPT 81479 is appropriate. Additionally, if a service meets the definition of a CGP but NOT 81459, CPT code 81479 is appropriate.

Therefore, to report a CGP service, test providers should use CPT codes 81459 or 81479, in addition to the approved DEX Z-Code® for the test. Coverage of CGPs is limited to one test per surgical specimen and precludes the use of any further 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
03/21/2024	R8	Under **Article Title** revised to MolDX: Targeted and Comprehensive Genomic Profile Testing in Cancer. Under **Article Text** subsection heading Next Generation Sequencing (NGS) 2nd sentence revised "tumor tissue only-based panels" to read "tumor-based panels for cancer that may be performed by NGS". Added verbiage and hyperlink for "Refer to MolDX: Defining panel services in MolDX A59687 for further guidance on the distinction between single analyte tests and panel tests". Under subsection heading Targeted Tumor Panels revised 1st sentence "Targeted Next-Generation Sequencing (NGS) panels" to read "Targeted tumor panels". Revised 2nd sentence to read "Generally, these panels are limited to specific variant types at defined sites, such as single nucleotide variants (SNVs), small insertions or deletions (INDELs), single site copy number variants, or gene fusions". Revised last sentence to delete "regions in the genes" and replaced with "targets". Under subsection heading Comprehensive Genomic Profile (CGP) Testing revised 1st sentence "CGP" to read "CGP testing". Revised 4th sentence "CGP" to read "CGP tests" and replaced "copy number alterations (CNAs)" with "copy number variants (CNVs)". Revised 5th sentence to add "and chromosome abnormalities such as loss of heterozygosity (LOH)". Revised 6th sentence "CGP" to read "CGP testing". Added new sentences "CGP tests are expected to yield information of clinical relevance beyond a targeted panel, for example, to identify relevant clinical trials for patient management or identify possible therapeutic interventions for off-label use. It is expected that a CGP will identify all clinically relevant information attainable for the type of service performed". Revised subsection heading "Targeted Panels" to read "Targeted Tumor Panels". Revised 1 st sentence to read "To bill for DNA-based panels that measure SNVs, INDELs, CNVs or rearrangements, review CPT codes 81445 and 81450" and deleted 2nd and 3rd sentences. Added new sentences "If a DNA-based targeted panel meeting the coverage requirements is used, and MSI is also performed, 81457 can be billed. If a DNA-based targeted test meeting coverage requirements is performed that includes MSI and CNVs, 81458 can be billed" and 2 new paragraphs. Revised last paragraph "DEX Z-Code™" to read "DEX Z-Code®". Under subsection heading CGP deleted first paragraph and added new paragraph. Revised 2nd paragraph 1st sentence to add "81459 or" and replaced "DEX Z-

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		Code™" with "DEX Z-Code®". Revised 2nd sentence to replace "other" with "further". Revised 3rd paragraph sentence "DEX Z-Code™" to read "DEX Z-Code®". Formatting, punctuation, and typographical errors were corrected throughout the article.
03/16/2022	R7	Updated to indicate this article is an LCD Reference Article.
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 **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,

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		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. 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,

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		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
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UPDATED ON	EFFECTIVE DATES	STATUS
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