

Article - Billing and Coding: MolDX: Testing of Multiple Genes (A58121)

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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
A58121

Article Title

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

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Article Type

Billing and Coding

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N/A

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N/A

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CMS National Coverage Policy

Title XVIII of the Social Security Act, §1862(a)(1)(A) allows coverage and payment for only those services that are considered to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII of the Social Security Act, §1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

Title 42 CFR §410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions

Article Guidance

Article Text

A panel of genes is a distinct procedural service from a series of individual genes. All services billed to Medicare must be reasonable and necessary. As such, if a provider or supplier submits a claim for a panel, then the patient's medical record must reflect that the panel was reasonable and necessary. Alternatively, if a provider or supplier bills for a number of individual genes, then the patient's medical record must reflect that each individual gene is reasonable and necessary.

Refer to [Billing and Coding: MoIDX: Molecular Diagnostic Tests \(MDT\) A57527](#) CPT/HCPCS Codes that are applicable to this article.

For ease of reading the term "gene" when used in this document will be used to indicate a gene, region of a gene, and / or variant(s) of a gene.

Genes can be assayed serially or in parallel. Genes assayed on the same date of service are considered to be assayed

in parallel if the result of 1 assay does not affect the decision to complete the assay on another gene, and the 2 genes are being tested for the same indication. Genes assayed on the same date of service are considered to be assayed serially when there is a reflexive decision component where the results of the analysis of 1 or more genes determines whether the results of additional analyses are reasonable and necessary.

If a laboratory assays 2 or more genes in a patient in parallel, then those 2 or more genes will be considered part of the same panel. A panel constitutes a single procedural service, so 1 HCPCS codes must be submitted for the panel. If the laboratory assays genes in serial, then the laboratory must submit claims for genes individually. The order by the treating clinician must reflect whether the treating clinician is ordering a panel or single genes, and additionally, the patient's medical record must reflect that the service billed was reasonable and necessary.

Two examples:

Single Service Example: A clinician orders 5 specific genes associated with breast cancer. The laboratory analyzes the 5 genes for common mutations using polymerase chain reaction. All 5 PCR procedures are started prior to the results of any 1 PCR procedure being known. The results are signed off on simultaneously, and all 5 results are sent to a clinician.

This would be considered a single procedural service, a single 5 gene panel, and it must be billed as such. This single panel must be reasonable and necessary to be billed to Medicare.

Multiple Distinct Procedural Services Example: A clinician requests that genes associated with early onset colorectal cancer be analyzed in a patient. The clinician orders stepwise reflex testing where a negative or positive result in 1 gene determines whether additional analysis on other genes will be performed or what that will be.

Each gene assayed represents 1 procedural service, so if more than 1 gene is analyzed, then multiple procedural services may be billed in some patients for whom reflex testing goes beyond the first gene. Each gene billed to Medicare must be individually reasonable and necessary. A clinician's order is not by itself sufficient to indicate that a test was reasonable and necessary. The record must reflect that the test is used in the management of the beneficiary's specific medical problem in accordance with CFR §410.32.

Labs must register a test with the Diagnostics Exchange as it reflected on the order form and is run in the laboratory. If a gene / variant is tested as part of a panel, then the lab must register the panel and must submit the correct z-code and CPT code for the panel. If a lab has a panel but sometimes also analyzes individual genes from the panel, the lab must register both the panel and the individual genes that are analyzed.

In general 2 or more codes describing a genetic test billed on the same beneficiary on the same date may constitute a panel, and if so the service must be billed as a single procedural service. We would generally expect that a provider or supplier would not bill for more than 2 distinct laboratory genetic testing procedural services on a single beneficiary on a single date of service. If providers or suppliers do bill for more than two distinct laboratory genetic testing procedural services on a single beneficiary on a single date of service, the provider or supplier must attest that each additional service billed is a distinct procedural service using the 59 modifier.

The use of the 59 modifier will be considered an attestation that distinct procedural services are being performed rather than a panel. Providers and suppliers must use the 59 modifier in conjunction with other modifiers where appropriate. When providers and suppliers bill for multiple distinct procedural services, each service must be reasonable and necessary.

Laboratories that are billing for many individual genes using the 59 modifier rather than panels may be subject to medical review as outliers.

When 2 or more codes are submitted for the same beneficiary on the same date of service, the claims processing system will reject every code submitted after the first service. However, if a lab runs more than 1 distinct procedural service on a single date of service, then the lab must use the 59 modifier with each additional service billed as an attestation that it is a distinct procedural service.

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: (1 Code)

CODE	DESCRIPTION
59	DISTINCT PROCEDURAL SERVICE: UNDER CERTAIN CIRCUMSTANCES, THE PHYSICIAN MAY NEED TO INDICATE THAT A PROCEDURE OR SERVICE WAS DISTINCT OR INDEPENDENT FROM OTHER SERVICES PERFORMED ON THE SAME DAY. MODIFIER -59 IS USED TO IDENTIFY PROCEDURES/SERVICES THAT ARE NOT NORMALLY REPORTED TOGETHER, BUT ARE APPROPRIATE UNDER THE CIRCUMSTANCES. THIS MAY REPRESENT A DIFFERENT SESSION OR PATIENT ENCOUNTER, DIFFERENT PROCEDURE OR SURGERY, DIFFERENT SITE OR ORGAN SYSTEM, SEPARATE INCISION/EXCISION, SEPARATE LESION, OR SEPARATE INJURY (OR AREA OF INJURY IN EXTENSIVE INJURIES) NOT ORDINARILY ENCOUNTERED OR PERFORMED ON THE SAME DAY BY THE SAME PHYSICIAN. HOWEVER, WHEN ANOTHER ALREADY ESTABLISHED MODIFIER IS APPROPRIATE IT SHOULD BE USED RATHER THAN MODIFIER -59. ONLY IF NO MORE DESCRIPTIVE MODIFIER IS AVAILABLE, AND THE USE OF MODIFIER -59 BEST EXPLAINS THE CIRCUMSTANCES, SHOULD MODIFIER -59 BE USED. MODIFIER CODE 09959 MAY BE USED AS AN ALTERNATE TO MODIFIER -59.

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
02/10/2022	R2	<p>Under Article Text added the verbiage: "Refer to Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57527 for CPT/HCPCS Codes that are applicable to this article" after the first sentence. Under CPT/HCPCS Codes Group 1: Paragraph deleted the verbiage and moved it to the end of the Article Text section. Under CPT/HCPCS Codes Group 1: Codes deleted all codes. Deleted CPT/HCPCS Codes Group 2: Paragraph, CPT/HCPCS Codes Group 2: Codes, and CPT/HCPCS Modifiers Group 2: Codes.</p> <p>12/17/2021: Under CPT/HCPCS Modifiers: added 59 modifier to group 2. Noridian has modified certain language in this article to mirror the language used presently by the MoIDX team at Palmetto GBA as part of an annual review. Revision history dates and language may not exactly match the MoIDX PGBA revision history. However, these revision do not change coverage or guidance.</p>
07/22/2021	R1	<p>Under Article Text-Multiple Distinct Procedural Services Example revised the fourth paragraph to read, "In general 2 or more codes describing a genetic test billed on the same beneficiary on the same date may constitute a panel, and if so the service must be billed as a single procedural service. We would generally expect that a provider or supplier would not bill for more than 1 distinct laboratory genetic testing procedural services on a single beneficiary on a single date of service. If providers or suppliers do bill for more than 1 distinct laboratory genetic testing procedural services on a single beneficiary on a single date of service, the provider or supplier must attest that each additional service billed is a distinct procedural service using the 59 modifier".</p> <p>Under CPT/HCPCS Codes Group 1: Paragraph revised the verbiage to read, "When 2 or more codes from this list are submitted for the same beneficiary on the same date of</p>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		service, the claims processing system will reject every code submitted after the first service. However, if a lab runs more than 1 distinct procedural service from this list on a single date of service, then the lab must use the 59 modifier with each additional service billed as an attestation that it is a distinct procedural service". Formatting, punctuation and typographical errors were corrected throughout the article.

Associated Documents

Related Local Coverage Documents

N/A

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
02/10/2022	02/10/2022 - N/A	Currently in Effect (This Version)
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04/23/2020	06/07/2020 - 07/21/2021	Superseded

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N/A