Article

Article - MolDX: Clarification of Order Requirements for Laboratory and Molecular Diagnostic services (A59744)

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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
A59744

Article Title
MolDX: Clarification of Order Requirements for Laboratory and Molecular Diagnostic services

Article Type
Article

Original Effective Date
05/02/2024

Revision Effective Date
N/A

Revision Ending Date
N/A

Retirement Date
N/A

Article Guidance

Article Text

Documentation requirements for laboratory services require that services be ordered by a treating physician as defined in IOM 100-02 Chapter 15 §80.6.1 and meet other criteria set in 42CFR(b) §410.32. Further clarifications were made in ICN MLN909221, December 2020.

In view of these requirements, this contractor provides the following supplemental clarifying information:

- Pathologists may order molecular diagnostic services when they fall under exemptions to the "treating physician" requirements as defined in the Medicare Benefits Manual 100-02 Chapter 15 sections 80.6.3, 80.6.4, or 80.6.5. Most commonly, pathologists may order molecular diagnostic tests when performing diagnostic services from a sample submitted to them without a specific test order. In such instances, the pathologist must meet all the criteria listed in section 80.6.5. This includes ensuring the service is reasonable and necessary, the results are communicated, and that the pathologist documents why the service was performed in their report. A pathologist may also order additional testing as defined in the above exemptions after the completion of an ordered service (molecular pathology or other pathology service) when that service

is medically necessary and a delay in the performance of the test would have an adverse effect on the care of the beneficiary.

- Test requisition forms are part of the medical record. When requisition forms include complete information validating medical necessity, such as qualifying clinical information that demonstrate test coverage criteria are met, the requisition form may be sufficient to determine if the service is reasonable and necessary without other medical information from the ordering provider. If the requisition form does NOT contain sufficient and relevant clinical information to determine if the service is reasonable and necessary for the intended patient, the requisition form is NOT considered sufficient to meet reasonable and necessary requirements and additional documentation may be required to fulfil this criteria.
- A "wet signature" is NOT required for clinical diagnostic tests and electronic signatures are acceptable if they confer an attestation that the physician is placing the order. A signature is also not required on orders for clinical diagnostic tests paid on the basis of the clinical lab fee schedule, the physician fee schedule, or for physician pathology services (IOM 100-02 Chapter 15 §80.6.1), provided that there is other evidence in the medical record that there is intent to place an order. However, it should be understood by providers that the most common reason for improper payment upon review is insufficient documentation, and it is best practice to ensure there is a singed order in place.

Coding Information

CPT/HCPCS Codes

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

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION

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
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