Local Coverage Determination (LCD):
MolDX: Molecular Diagnostic Tests (MDT) (L36256)

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
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

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LCD Information

Document Information

Original Effective Date
For services performed on or after 10/01/2015

LCD ID
L36256

Revision Effective Date
For services performed on or after 01/01/2018

LCD Title
MolDX: Molecular Diagnostic Tests (MDT)

Revision Ending Date
N/A

Proposed LCD in Comment Period
N/A

Retirement Date
N/A

Source Proposed LCD
N/A

Notice Period Start Date
08/16/2015

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

Notice Period End Date
09/30/2015

CMS National Coverage Policy Title XVIII of the Social Security Act (SSA) §1862(a)(1)(A), states that no Medicare payment shall be made for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of malformed body member."

Title XVIII of the Social Security Act (SSA) §1833(e), prohibits Medicare payment for any claim lacking the necessary documentation to process the claim.

Title XVIII of the Social Security Act (SSA) §1862(a)(1)(D), Investigational or Experimental.

CMS Manual System, Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, §80.1, 80.1.1, 80.1.2, 80.1.3, laboratory services must meet applicable requirements of CLIA.

Pub 100-08 PIM, Ch. 13, Sec 13.1.3, Program Integrity Manual, *LCDs consist of only "reasonable and necessary"* information.

Coverage Guidance
Coverage Indications, Limitations, and/or Medical Necessity

This coverage policy provides the following information:

• defines tests required to register for a unique identifier
• defines tests required to submit a complete technical assessment (TA) for coverage determination
• defines the payment rules applied to covered tests that are not reported with specific CPT codes
• lists some examples of specific covered tests that have completed the registration and TA process and meet Medicare's reasonable and necessary criteria for coverage. This listing is not inclusive.

Tests evaluated through the application process and/or technical assessment will be reviewed to answer the following questions:

• Is the test performed in the absence of clinical signs and symptoms of disease?
• Will the test results provide the clinician with information that will improve patient outcomes and/or change physician care and treatment of the patient?
• Will the test results confirm a diagnosis or known information?
• Is the test performed to determine risk for developing a disease or condition?
• Will risk assessment change management of the patient?

• Is there a diagnosis specific indication to perform the test?
• Is the test performed to measure the quality of a process or for Quality Control/Quality Assurance (QC/QA), i.e., a test to ensure a tissue specimen matches the patient?

MDT Policy Specific Definitions

MDT: Any test that involves the detection or identification of nucleic acid(s) (DNA/RNA), proteins, chromosomes, enzymes, cancer chemotherapy sensitivity and/or other metabolite(s). The test may or may not include multiple components. A MDT may consist of a single mutation analysis/identification, and/or may or may not rely upon an algorithm or other form of data evaluation/derivation.

LDT: Any test developed by a laboratory developed without FDA approval or clearance.

Applicable Tests/Assays

In addition to the MDT definition, this coverage policy applies to all tests that meet at least one of the following descriptions:
• All non-FDA approved/cleared laboratory developed tests (LDT)
• All modified FDA-approved/cleared kits/tests/assays
• All tests/assays billed with more than one CPT code to identify the service, including combinations of method-based, serology-based, and anatomic pathology codes
• All tests that meet the first three bullets and are billed with an NOC code

Unique Test Identifier Requirement

Because the available language in the HCPCS and CPT manuals to describe the pathology and laboratory categories and the tests included in those categories are not specific to the actual test results provided, all MDT services must include an identifier as additional claim documentation. Test providers must apply for an identifier specific to the applicable test and submit the test assigned identifier with the claim for reimbursement. The assigned identifier will provide a crosswalk between the test's associated detail information on file and the submitted claim detail line(s) required to adjudicate each test's claim. The unique identifier limits the need to submit the required additional information about the test on each claim.

Laboratory providers who bill MDT services must register services on the DEX™ Diagnostics Exchange.

Technology Assessments (TA)

MolDX will review all new test/assay clinical information to determine if a test meets Medicare's reasonable and necessary requirement. Labs must submit a comprehensive dossier on each new test/assay prior to claim submission. MolDX will only cover and reimburse tests that demonstrate analytical and clinical validity, and clinical utility at a level that meets the Medicare reasonable and necessary requirement.

Payment Rules

MolDX will reimburse:

• approved tests covered for dates of service consistent with the effective date of the coverage determination.

Covered Tests

Please refer to the Noridian website for covered tests' specific coding and billing information.

Other tests/assays may be covered by separate Noridian policy. In addition the CPT codes listed under Group 1 are covered. If a test is not listed, it may be covered under separate Noridian policy or it has not been approved for coverage as it has either not been vetted by the MolDx contractor or has been found to be considered statutorily excluded. A list of approved tests may be found on the Noridian webpage.

To obtain a unique identifier for a test and, to submit information for a technical assessment go to DEX™ Diagnostics Exchange:https://app.mckessondex.com/#login.

For additional MolDX Program information, go to the Noridian Medicare home page at noridianmedicare.com and select MolDX under the Policies Tab.

MolDX expects laboratory providers to follow test indications published by the developer.

Summary of Evidence

NA

Analysis of Evidence
(Rationale for Determination)

NA

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Coding Information

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 policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy 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 policy, 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 policy should be assumed to apply equally to all Revenue Codes.

N/A
CPT/HCPCS Codes
Group 1 Paragraph: N/A

Group 1 Codes:

81161 - 81599	Dmd dup/delet analysis - Unlisted maaa
84999	Clinical chemistry test
85999	Hematology procedure
86849	Immunology procedure
87999	Microbiology procedure
88199	Cytopathology procedure
88299	Cytogenetic study
88380	Microdissection laser
88381	Microdissection manual
88399	Surgical pathology procedure
89398	Unlisted reprod med lab proc
G0452	Molecular pathology interpr
0001M	Infectious dis hcv 6 assays
0002M	Liver dis 10 assays w/ash
0003M	Liver dis 10 assays w/nash

0004M	Scoliosis dna alys
0006M	Onc hep gene risk classifier
0007M	Onc gastro 51 gene nomogram
0008M	Onc breast risk score
0009M	Fetal aneuploidy trisom risk

ICD-10 Codes that Support Medical Necessity
Group 1 Paragraph: N/A

Group 1 Codes:

ICD-10 Codes	Description
XX000	Not Applicable

ICD-10 Codes that DO NOT Support Medical Necessity
Group 1 Paragraph: N/A

Group 1 Codes:

ICD-10 Codes	Description
XX000	Not Applicable

ICD-10 Additional Information Back to Top

General Information

Associated Information

Sources of Information
1. Current Procedural Terminology® (CPT) American Medical Association. American Medical Association Press, ISBN9781603592178, 2011.
Bibliography

NA
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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
01/01/2018	R3	The following changes were made as a result of the Annual 2018 CPT/HCPCS code update: 81175, 81176, 81230, 81231, 81232, 81238, 81247, 81248, 81249, 81258, 81259, 81269, 81283, 81328, 81334, 81335, 81346, 81361, 81362, 81363, 81364, 81448, 81520, 81521, 81541 and 81551 were added to code range 81161 - 81599 in Group 1. CPT codes are current as of the AMA CPT® 2018 Professional Edition, ISBN 978-1-62202-600-5, ISSN 0276-8283. 12/5/2017 At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.	• Creation of Uniform LCDs With Other MAC Jurisdiction • Revisions Due To CPT/HCPCS Code Changes

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
01/01/2017	R2	2017 CPT Code Changes: The following CPT/HCPCS codes were added to these code ranges: 81327 was added to code range 81161 - 81599 in Group 1 81413 was added to code range 81161 - 81599 in Group 1 81414 was added to code range 81161 - 81599 in Group 1 81422 was added to code range 81161 - 81599 in Group 1 81439 was added to code range 81161 - 81599 in Group 1 81539 was added to code range 81161 - 81599 in Group 1 Description was changed for the following CPT/HCPCS codes: 81402 descriptor was changed in Group 1, 81407 descriptor was changed in Group 1 CPT/HCPCS codes were deleted: 0010M, 81280, 81281 and 81282 was deleted from Group 1.	• Revisions Due To CPT/HCPCS Code Changes
04/21/2016	R1	Replaced Palmetto GBA reference with MolDX, Under "Unique Test Identifier Requirement" - removed instruction to register services via Z-Code Identifier Application and Palmetto GBA Test Identifier (PTI) Application. Under "Payment Rules" - removed suspension of claims that omit Z-Code IDs. Under "Covered Tests" - updated the point of contact for McKesson and MolDX.) JFA LCD L36255 is retired and JFA contract numbers are added to the JFB LCD so that JFA and JFB have the same MCD LCD number.	• Creation of Uniform LCDs With Other MAC Jurisdiction

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Associated Documents

Attachments MolDX Approved Gene Testing (PDF - 72 KB)

Related Local Coverage Documents Article(s) A54358 - MolDX: Afirma™ Assay by Veracyte Billing and Coding Guidelines A54366 - MolDX: AlloMap Billing and Coding Guidelines A54378 - MolDX: Avise PG Assay Billing and Coding Guidelines A54388 - MolDX: bioTheranostics Cancer TYPE ID® Billing and Coding Guidelines A54431 - MolDX: Corus® CAD Test Billing and Coding Guidelines A55186 - MolDX: FDA Approved ALK Companion Diagnostic Tests Billing and Coding Guidelines A54420 - MolDX: FDA-Approved BRAF Tests Billing and Coding Guidelines A54424 - MolDX: FDA-Approved EGFR Tests Billing and Coding Guidelines A54500 - MolDX: FDA-Approved KRAS Tests A54439 - MolDX: HERmark® Assay by Monogram Billing and Coding Guidelines A54447 - MolDX: MammaPrint Billing and Coding Guidelines A54482 - MolDX: Oncotype DX® Breast Cancer Assay Billing and Coding Guidelines A54486 - MolDX: Oncotype DX® Colon Cancer Coding and Billing Guidelines A54492 - MolDX: Progensa® PCA3 Assay Billing and Coding Guidelines A54496 - MolDx: ResponseDX Tissue of Origin® Billing and Coding Guidelines A54505 - MolDX: Vectra™ DA Billing and Coding Guidelines A54511 - MolDX: Vysis® Kit by Abbott Coding and Billing Guidelines A54554 - Response to Comments: MolDX: Molecular Diagnostic Tests (MDT)

Related National Coverage Documents N/A

Public Version(s) Updated on 12/06/2017 with effective dates 01/01/2018 - N/A Updated on 01/06/2017 with effective dates 01/01/2017 - 12/31/2017 Updated on 08/04/2016 with effective dates 04/21/2016 - 12/31/2016 Updated on 07/10/2015 with effective dates 10/01/2015 - N/A Back to Top

Keywords

- Afirma

- Allomap
- Avise PG
- Cancer TYPE ID
- cobas 4800 BRAF V600
- cobas EGFR
- ConfirmMDx Epigenetic Molecular Assay
- Corus CAD
- HERmark
- MammaPrint
- Oncotype DX Breast
- Oncotype DX Colon
- Progensa PCA3
- therascreen EGFR
- therascreen KRAS
- Tissue of Origin
- THXID BRAF V600E/K Test
- Vectra DA
- Vysis
- MolDX

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