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

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

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

Back to Top

LCD Information

Document Information

LCD ID
L36256

LCD Title
MolDX: Molecular Diagnostic Tests (MDT)

Proposed LCD in Comment Period
N/A

Source Proposed LCD
N/A

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

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

Revision Effective Date
For services performed on or after 06/21/2018

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
08/16/2015

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.dexzcodes.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

Back to Top

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:

81105 - 81112	Hpa-1 genotyping - Hpa-15 genotyping
81120 - 81121	Idh1 common variants - Idh2 common variants
81161 - 81599	Dmd dup/delet analysis - Unlisted maaa
84999	Clinical chemistry test
85999	Hematology procedure
86152 - 86153	Cell enumeration & id - Cell enumeration phys interp
86849	Immunology procedure
88120 - 88121	Cytp urne 3-5 probes ea spec - Cytp urine 3-5 probes cmptr
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
0009M	Fetal aneuploidy trisom risk
0011M	Onc prst8 ca mrna 12 gen alg
0012M	Onc mrna 5 gen rsk urthl ca
0013M	Onc mrna 5 gen recr urthl ca
0001U	Rbc dna hea 35 ag 11 bld grp
0002U	Onc clrct 3 ur metab alg plp
0003U	Onc ovar 5 prtn ser alg scor
0005U	Onco prst8 3 gene ur alg
0006U	Detc ia meds 120+analytes
0007U	Rx test prsmv ur w/def conf
0008U	Hpylori detcj abx rstnc dna
0009U	Onc brst ca erbb2 amp/nonamp
0010U	Nfct ds strn typ whl gen seq
0011U	Rx mntr lc-ms/ms oral fluid
0012U	Germln do gene reargmt detcj
0013U	Onc sld org neo gene reargmt
0014U	Hem hmtlmf neo gene reargmt
0016U	Onc hmtlmf neo rna bcr/abl1
0017U	Onc hmtlmf neo jak2 mut dna
0018U	Onc thyr 10 microrna seq alg
0019U	Onc rna tiss predict alg
0020U	Rx test prsmv ur w/def conf
0021U	Onc prst8 detcj 8 autoantb
0022U	Trgt gen seq dna&rna 23 gene
0023U	Onc aml dna detcj/nondetcj
0024U	Glyca nuc mr spectrsc quan
0025U	Tenofovir liq chrom ur quan
0026U	Onc thyr dna&mrna 112 genes
0027U	Jak2 gene trgt seq alys
0028U	Cyp2d6 gene cpy nmr cmn vrnt
0029U	Rx metab advrs trgt seq alys
0030U	Rx metab warf trgt seq alys
0031U	Cyp1a2 gene
0032U	Comt gene
0033U	Htr2a htr2c genes
0034U	Tpmt nudt15 genes
0035U	Neuro csf prion prtn qual
0036U	Xome tum & nml spec seq alys
0037U	Trgt gen seq dna 324 genes
0038U	Vitamin d srm microsamp quan
0039U	Dna antb 2strand hi avidity
0040U	Bcr/abl1 gene major bp quan
0041U	B brgdrferi antb 5 prtn igm
0042U	B brgdrferi antb 12 prtn igg
0043U	Tbrf b grp antb 4 prtn igm
0044U	Tbrf b grp antb 4 prtn igg

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

Back to Top

Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
06/21/2018	R5	Removed: 88399, 89398, 87999, 88199, 88299 Added: 0001U, 0002U, 0003U, 0005U, 0006U, 0007U, 0008U, 0009U, 0010U, 0011U, 0012U, 0013U, 0014U, 0016U, 0017U, 0018U, 0019U, 0020U, 0021U, 0022U, 0023U, 0024U, 0025U, 0026U, 0027U, 0028U, 0029U, 0030U, 0031U, 0032U, 0033U, 0034U, 0035U, 0036U, 0037U, 0038U, 0039U, 0040U, 0041U, 0042U, 0043U, 0044U, 0011M, 0012M, 0013M, 81105-81112, 81120-81121, 86152-86153, 88120-88121. Removed G0452, 88380, 88381 because they no longer require a DEX Z code identifier. Revised the link for technical assessment information.	• Creation of Uniform LCDs With Other MAC Jurisdiction • Revisions Due To CPT/HCPCS Code Changes
01/01/2018	R4	03/29/2018: 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
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.	• 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
		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.	
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

Back to Top

Associated Documents

Attachments N/A

Related Local Coverage Documents Article(s) A55712 - MolDX: Abbott RealTime IDH2 testing for Acute Myeloid Leukemia (AML) Billing and Coding Guidelines A55888 - MolDX: ThermoFisher Oncomine Dx Target Test For Non-Small Cell Lung Cancer Billing and Coding Guidelines 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 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 A55295 - MolDX: Myriad's BRACAnalysis CDx™ 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 A54554 - Response to Comments: MolDX: Molecular Diagnostic Tests (MDT) A54431 - (MCD Archive Site) A54511 - (MCD Archive Site)

Related National Coverage Documents N/A

Public Version(s) Updated on 07/05/2018 with effective dates 06/21/2018 - N/A Updated on 04/10/2018 with effective dates 01/01/2018 - 06/20/2018 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 Some older versions have been archived. Please visit the MCD Archive Site to retrieve them. 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

Read the **LCD Disclaimer** Back to Top