

Local Coverage Determination (LCD): MoIDX: Molecular Diagnostic Tests (MDT) (L35160)

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Contractor Information

| CONTRACTOR NAME | CONTRACT TYPE | CONTRACT NUMBER | JURISDICTION | STATE(S) |
|------------------------------------|---------------|-----------------|--------------|---|
| Noridian Healthcare Solutions, LLC | A and B MAC | 01111 - MAC A | J - E | California - Entire State |
| Noridian Healthcare Solutions, LLC | A and B MAC | 01112 - MAC B | J - E | California - Northern |
| Noridian Healthcare Solutions, LLC | A and B MAC | 01182 - MAC B | J - E | California - Southern |
| Noridian Healthcare Solutions, LLC | A and B MAC | 01211 - MAC A | J - E | American Samoa Guam Hawaii Northern Mariana Islands |
| Noridian Healthcare Solutions, LLC | A and B MAC | 01212 - MAC B | J - E | American Samoa Guam Hawaii Northern Mariana Islands |
| Noridian Healthcare Solutions, LLC | A and B MAC | 01311 - MAC A | J - E | Nevada |
| Noridian Healthcare Solutions, LLC | A and B MAC | 01312 - MAC B | J - E | Nevada |
| Noridian Healthcare Solutions, LLC | A and B MAC | 01911 - MAC A | J - E | American Samoa California - Entire State Guam Hawaii Nevada Northern Mariana Islands |

LCD Information

Document Information

LCD ID

L35160

Original ICD-9 LCD ID

[L33541](#)

LCD Title

MoIDX: Molecular Diagnostic Tests (MDT)

Proposed LCD in Comment Period

N/A

Source Proposed LCD

N/A

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Original Effective Date

For services performed on or after 10/01/2015

Revision Effective Date

For services performed on or after 01/01/2019

Revision Ending Date

N/A

Retirement Date

N/A

Notice Period Start Date

08/16/2015

Notice Period End Date

09/30/2015

or Laryssa Marshall at (312) 893-6814. You may also contact us at ub04@healthforum.com.

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)

MoIDX 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. MoIDX 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

MoIDX 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 MoIdx contractor or has been found to be considered statutorily excluded. A list of approved tests may be found on the Noridian website.

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

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

Summary of Evidence

NA

Analysis of Evidence (Rationale for Determination)

NA

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:

| CODE | DESCRIPTION |
|---------------|--|
| 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 |
| 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 |

| CODE | DESCRIPTION |
|-------|------------------------------|
| 0018U | Onc thyr 10 microrna seq alg |
| 0019U | Onc rna tiss predict alg |
| 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 |
| 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 CODE | DESCRIPTION |
|-------------|----------------|
| XX000 | Not Applicable |

ICD-10 Codes that DO NOT Support Medical Necessity

N/A

Additional ICD-10 Information

N/A

General Information

Associated Information

N/A

Sources of Information

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

Bibliography

NA

Revision History Information

| REVISION HISTORY DATE | REVISION HISTORY NUMBER | REVISION HISTORY EXPLANATION | REASON(S) FOR CHANGE |
|-----------------------|-------------------------|---|--|
| 01/01/2019 | R8 | Corrected typographical error in R7 revision history: CPT codes 71178, 71179, 71180 should be 81178, 81179 and 81180. | <ul style="list-style-type: none">• Typographical Error |
| 01/01/2019 | R7 | <p>The following updates were made as a result of the 2019 Annual HCPCS code update:</p> <p>Deleted codes:0001M, 81211, 81213, 81214</p> <p>Codes added to existing ranges: 81163, 81164, 81165, 81166, 81167, 81171, 81172, 81173, 81174, 81177, 71178, 71179, 71180, 81181, 81182, 81183, 81184, 81185, 81186, 81187, 81188, 81189, 81190, 81204, 81233, 81234, 81236, 81237, 81239, 81237, 81239, 81271, 81274, 81284, 81285, 81286, 81289, 81305 ,81306, 81312, 80320, 81329, 81333, 81336, 81337, 81343, 81344,81345, 81443, 81518,81596</p> <p>Codes with descriptor changes: 0006U, 0012M, 0031U, 0032U, 81109, 81162, 81212, 81215, 81216, 81217, 81244, 81287,</p> | <ul style="list-style-type: none">• 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 |
|-----------------------|-------------------------|---|---|
| | | 81327, 81334 | |
| 06/21/2018 | R6 | <p>Removed: 88399, 89398, 87999, 88199, 88299</p> <p>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.</p> | <ul style="list-style-type: none"> • Creation of Uniform LCDs With Other MAC Jurisdiction • Revisions Due To CPT/HCPCS Code Changes |
| 01/01/2018 | R5 | <p>Removed G0452, 88380, 88381 because they no longer require a DEX Z code identifier. Revised the link for technical assessment information.</p> <p>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.</p> | <ul style="list-style-type: none"> • Creation of Uniform LCDs With Other MAC Jurisdiction |
| 01/01/2018 | R4 | <p>The following changes were made as a result of the Annual 2018 CPT/HCPCS code update:</p> <p>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.</p> <p>CPT codes are current as of the AMA CPT® 2018 Professional Edition, ISBN 978-1-62202-600-5, ISSN 0276-8283.</p> <p>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</p> | <ul style="list-style-type: none"> • 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 |
|-----------------------|-------------------------|---|--|
| | | included on the LCD are applicable as noted in this policy. | |
| 01/01/2017 | R3 | <p>2017 CPT Code Changes: The following CPT/HCPCS codes were added to these code ranges:</p> <p>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</p> <p>Description was changed for the following CPT/HCPCS codes: 81402 descriptor was changed in Group 1, 81407 descriptor was changed in Group 1</p> <p>CPT/HCPCS codes were deleted: 0010M, 81280, 81281 and 81282 was deleted from Group 1.</p> | <ul style="list-style-type: none"> Revisions Due To CPT/HCPCS Code Changes |
| 04/21/2016 | R2 | Replaced Palmetto GBA reference with MoIDX, 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 MoIDX.) JEA LCD L36249 is retired and JEA contract numbers are added to the JEB LCD so that JEA and JEB have the same MCD LCD number. | <ul style="list-style-type: none"> Creation of Uniform LCDs With Other MAC Jurisdiction |
| 10/01/2015 | R1 | This LCD is the final ICD-10 version of DL33541 Molecular Diagnostic Tests (MDT), which was initially introduced into draft in ICD-9 format and finalized in ICD-10 format. | <ul style="list-style-type: none"> Creation of Uniform LCDs Within a MAC Jurisdiction Creation of Uniform LCDs With Other MAC Jurisdiction |

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A55711 - MoIDX: Abbott RealTime IDH2 testing for Acute Myeloid Leukemia (AML) Billing and Coding Guidelines

A55881 - MoIDX: ThermoFisher Oncomine Dx Target Test For Non-Small Cell Lung Cancer Billing and Coding Guidelines

A54356 - MoIDX: Afirma™ Assay by Veracyte Billing and Coding Guidelines

A54364 - MoIDX: AlloMap Billing and Coding Guidelines

A54376 - MoIDX: Avise PG Assay Billing and Coding Guidelines

A54386 - MoIDX: bioTheranostics Cancer TYPE ID® Billing and Coding Guidelines

A55185 - MoIDX: FDA Approved ALK Companion Diagnostic Tests Billing and Coding Guidelines

A54418 - MoIDX: FDA-Approved BRAF Tests Billing and Coding Guidelines

A54422 - MoIDX: FDA-Approved EGFR Tests Billing and Coding Guidelines

A54498 - MoIDX: FDA-Approved KRAS Tests

A54437 - MoIDX: HERmark® Assay by Monogram Billing and Coding Guidelines

A54445 - MoIDX: MammaPrint Billing and Coding Guidelines

A55294 - MoIDX: Myriad's BRACAnalysis CDx™ Billing and Coding Guidelines

A54480 - MoIDX: Oncotype DX® Breast Cancer Assay Billing and Coding Guidelines

A54484 - MoIDX: Oncotype DX® Colon Cancer Coding and Billing Guidelines

A54489 - MoIDX: Progensa® PCA3 Assay Billing and Coding Guidelines

A54494 - MoIdx: ResponseDX Tissue of Origin® Billing and Coding Guidelines

A54503 - MoIDX: Vectra™ DA Billing and Coding Guidelines

A54552 - Response to Comments: MoIDX: Molecular Diagnostic Tests (MDT)

A54429

- (MCD Archive Site)A54509

- (MCD Archive Site)

Related National Coverage Documents

N/A

Public Version(s)

Updated on 12/19/2018 with effective dates 01/01/2019 - N/A

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Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

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
- theascreen EGFR
- theascreen KRAS
- Tissue of Origin
- THXID BRAF V600E/K Test
- Vectra DA
- Vysis
- MoIDX