### Contractor Information

<table>
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<tr>
<th>Contractor Name</th>
<th>Contract Type</th>
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<td>01111 - MAC A</td>
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### LCD Information

#### Document Information

- **LCD ID:** L35160
- **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

- **Original ICD-9 LCD ID:** L33541
- **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**
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 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 MolDX Program information, go to the Noridian Medicare home page at noridianmedicare.com and

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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

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 urine 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

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General Information

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Revision History Information

<table>
<thead>
<tr>
<th>Revision History Date</th>
<th>Revision History Number</th>
<th>Revision History Explanation</th>
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<td>06/21/2018</td>
<td>R6</td>
<td>Removed: 88399, 89398, 87999, 88199, 88299</td>
<td>• Creation of Uniform LCDs With Other MAC Jurisdiction</td>
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<tr>
<td>01/01/2018</td>
<td>R5</td>
<td>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. 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.</td>
<td>• Creation of Uniform LCDs With Other MAC Jurisdiction</td>
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<td>01/01/2018</td>
<td>R4</td>
<td>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. 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</td>
<td>• Revisions Due To CPT/HCPCS Code Changes</td>
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<td>01/01/2017</td>
<td>R3</td>
<td>Description was changed for the following CPT/HCPCS codes:</td>
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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.

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.) 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.

04/21/2016 R2

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.

10/01/2015 R1

Creation of Uniform LCDs Within a MAC Jurisdiction

Creation of Uniform LCDs With Other MAC Jurisdiction

Keywords

- Afirma
- Allomap
- Avise PG

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• 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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