## Contractor Information

<table>
<thead>
<tr>
<th>Contractor Name</th>
<th>Contract Type</th>
<th>Contract Number</th>
<th>Jurisdiction State(s)</th>
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<tr>
<td>Wisconsin Physicians Service Insurance Corporation</td>
<td>MAC - Part A</td>
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<td>J - 05</td>
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Local Coverage Determination (LCD): MolDX: Molecular Diagnostic Tests (MDT) (L36807)

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

### Document Information

- **LCD ID**: L36807
- **Original Effective Date**: For services performed on or after 02/16/2017
- **LCD Title**: MolDX: Molecular Diagnostic Tests (MDT)
- **Revision Effective Date**: For services performed on or after 01/01/2018
- **Proposed LCD in Comment Period**: N/A
- **Revision Ending Date**: N/A
- **Source Proposed LCD**: N/A
- **Retirement Date**: N/A

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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.

Change Request 9977 Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - April CY 2017 Update
Change Request 10104 Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - July CY 2017 Update
Change Request 10122 July 2017 Update of the Hospital Outpatient Prospective Payment System (OPPS)
Change Request 10222 Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) – October CY 2017 Update
Change Request 10236 SUBJECT: October 2017 Update of the Hospital Outpatient Prospective Payment System (OPPS)

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 specific covered tests that have completed the registration and TA process and meets Medicare's reasonable and necessary criteria for coverage.

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. An 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 test services on the McKesson 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 MoIDX website www.palmettogba.com/MoIDX for covered and excluded tests’ specific coding and billing information.

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

For additional MoIDX Program information, go to the Medicare home page at PalmettoGBA.com/MoIDX.

WPS GHA and the MoIDX Contractor expect 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:

81161 - 81599  Dmd dup/delet analysis - Unlisted maaa
84999  Clinical chemistry test
85999  Hematology procedure
86152  Cell enumeration & id
86153  Cell enumeration phys interp
86849  Immunology procedure
87149  Dna/rna direct probe
87150  Dna/rna amplified probe
87505  Nfct agent detection gi
87506  Iadna-dna/rna probe tq 6-11
87507  Iadna-dna/rna probe tq 12-25
87631 - 87633  Resp virus 3-5 targets - Resp virus 12-25 targets
87999  Microbiology procedure
88120  Cytpe urine 3-5 probes ea spec
88121  Cytpe urine 3-5 probes cmprtr
88199  Cytopathology procedure
88299  Cytogenetic study
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
**0001U - 0017U**  Rbc dna hea 35 ag 11 bld grp - Onc hmtlmf neo jak2 mut dna

ICD-10 Codes that Support Medical Necessity

**Group 1 Paragraph:**

NA

**Group 1 Codes:**

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<th>Description</th>
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ICD-10 Codes that DO NOT Support Medical Necessity

**Group 1 Paragraph:**

N/A

**Group 1 Codes:** N/A

ICD-10 Additional Information [Back to Top]

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**General Information**

Associated Information

N/A

Sources of Information

N/A

Bibliography

NA

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**Revision History Information**

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<th>Revision History Explanation</th>
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<td>01/01/2018</td>
<td>R3</td>
<td>01/01/2018-Code update added 81175, 81176, 81230-81232, 81238,81247-81249, 81258, 81259, 81269, 81105-81112, 81120, 81121, 81283,81328, 81334, 81335, 81346, 81361-81364, 81448, 81520, 81521 &amp; description change 81257, 81400, 81401, 81403-81406, 81432, 81439. Added 0001M, 87631-87633, 87149-87150 effective 02/15/2018.</td>
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10/01/2017  R2

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- Revisions Due To CPT/HCPCS Code Changes
10/01/2017: Added new codes 0004U & 0005U to the CPT table effective 05/01/2017 (Change Request (CR) 10104 & 10122) & added 0006U -0017U to CPT table; effective 08/01/2017 (CR 10222 & 10236). Moved 001U-003U from paragraph to CPT code table. Annual Review completed 09/08/2017. 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.

05/16/2017 R1 04/01/2017-Added CPT codes 86152, 86153, 87505-87507 & 0001U-0003U with 45 day notice-effective 05/16/2017 and removed CPT codes 88380 and 88381-effective 04/01/2017.

Related National Coverage Documents N/A

Public Version(s) Updated on 12/21/2017 with effective dates 01/01/2018 - N/A Updated on 09/18/2017 with effective dates 10/01/2017 - 12/31/2017 Updated on 03/20/2017 with effective dates 05/16/2017 - 09/30/2017 Updated on 12/20/2016 with effective dates 02/16/2017 - N/A

Keywords

N/A Read the LCD Disclaimer Back to Top