Local Coverage Determination (LCD):
MolDX: Molecular Diagnostic Tests (MDT) (L36807)

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05101 - MAC A	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05102 - MAC B	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05201 - MAC A	J - 05	Kansas
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05202 - MAC B	J - 05	Kansas
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05301 - MAC A	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05302 - MAC B	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05401 - MAC A	J - 05	Nebraska
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05402 - MAC B	J - 05	Nebraska
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05901 - MAC A	J - 05	Alaska Alabama Arkansas Arizona Connecticut Florida Georgia Iowa Idaho Illinois Indiana Kansas Kentucky Louisiana Massachusetts Maine Michigan Minnesota Missouri - Entire State Mississippi Montana North Carolina North Dakota Nebraska New Hampshire New Jersey Ohio Oregon Rhode Island South Carolina South Dakota Tennessee Utah

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
				Virginia Virgin Islands Vermont Washington Wisconsin West Virginia Wyoming
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	08101 - MAC A	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	08102 - MAC B	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	08201 - MAC A	J - 08	Michigan
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	08202 - MAC B	J - 08	Michigan

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LCD Information

Document Information

LCD ID
L36807

LCD Title
MolDX: Molecular Diagnostic Tests (MDT)

Proposed LCD in Comment Period
N/A

Source Proposed LCD
N/A

Original Effective Date
For services performed on or after 02/16/2017

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

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
01/01/2017

Notice Period End Date
02/15/2017

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)
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 MolDX website www.palmettogba.com/MolDX 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 MolDX Program information, go to the Medicare home page at PalmettoGBA.com/MolDX.

WPS GHA and the MolDX Contractor expect 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
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	Cytp urne 3-5 probes ea spec
88121	Cytp urine 3-5 probes cmptr
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:

ICD-10 Codes	Description
XX000	Not Applicable

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

General Information

Associated Information

N/A

Sources of Information

N/A

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	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 & description change 81257, 81400, 81401, 81403-81406, 81432, 81439. Added 0001M, 87631-87633, 87149-87150 effective 02/15/2018.	• Revisions Due To CPT/HCPCS Code Changes
10/01/2017	R2		

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
		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 0001U-0003U 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.	• Revisions Due To CPT/HCPCS Code Changes • Other (Annual Review)
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.	• Revisions Due To CPT/HCPCS Code Changes

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Associated Documents

Attachments N/A

Related Local Coverage Documents Article(s) A55137 - MolDX 4q25-AF Risk Genotype Testing Coding and Billing Guidelines A55738 - MolDX: Coding and Billing for Abbott RealTime IDH2 testing for Acute Myeloid Leukemia (AML) A55138 - MolDX: 9p21 Genotype Test Coding and Billing Guideline A55139 - MolDX: Afirma™ Assay by Veracyte Update A55140 - MolDX: AlloMap Billing and Coding Guidelines Update A55141 - MolDX: ApoE Genotype Coding and Billing Guidelines A55248 - MolDX: Approved Gene Testing A55235 - MolDX: Arrhythmogenic Right Ventricular Dysplasia/Cardiomyopathy (ARVD/C) Testing Coding and Billing Guidelines A55142 - MolDX: Aspartoacyclase 2 Deficiency (ASPA) Testing Coding and Billing Guidelines A55143 - MolDX: ATP7B Gene Tests Coding and Billing Guidelines A55144 - MolDX: Avise PG Assay Billing/Coding Update A55145 - MolDX: BCKDHB Gene Test Coding and Billing Guidelines A55233 - MolDx: BCR-ABL Coding and Billing Guidelines A55147 - MolDX: bioTheranostics Cancer TYPE ID® Update A55148 - MolDX: BLM Gene Analysis Coding and Billing Guidelines A55146 - MolDX: BluePrint® Coding and Billing Guidelines A55622 - MolDX: CDH1 Genetic Testing Coding and Billing Guidelines A55156 - MolDX: CFTR Gene Analysis Coding and Billing Guidelines A55157 - MolDX: CHD7 Gene Analysis Coding and Billing Guidelines A55234 - MolDX: CYP2B6 Test Coding and Billing Guidelines A55159 - MolDX: ENG and ACVRL1 Gene Tests Coding and Billing Guidelines A55247 - MolDX: Excluded Test List A55160 - MolDX: FANCC Genetic Testing Coding and Billing Guidelines A55161 - MolDX: FDA-Approved BRAF Tests A55193 - MolDX: FDA-Approved EGFR Tests A55162 - MolDX: FDA-Approved KRAS Tests A55163 - MolDX: Fragile X Coding and Billing Guidelines Update A55164 - MolDX: GBA Genetic Testing Coding and Billing Guidelines A55165 - MolDX: HAX1 Gene Sequencing Coding and Billing Guidelines A55166 - MolDX: HBB Gene Tests Coding and Billing Guidelines A55167 - MolDX: HERmark® Assay by Monogram A55168 - MolDX: HEXA Gene Analysis Coding and Billing Guidelines A55169 - MolDX: HTTLPR Gene Testing Coding and Billing Guidelines A55170 - MolDX: IKBKAP Genetic Testing Coding and Billing Guidelines A55171 - MolDX: KIF6 Genotype Billing and Coding Guidelines A55172 - MolDX: know error® Billing and Coding Guidelines Update A55192 - MolDX: L1CAM Gene Sequencing Coding and Billing Guidelines A55173 - MolDX: LPA-Aspirin Genotype Coding and Billing Guidelines A55174 - MolDX: LPA-Intron 25 Genotype Coding and Billing Guidelines A55175 - MolDX: MammaPrint Billing and Coding Guidelines Update A55176 - MolDX: MCOLN1 Genetic Testing Coding and Billing Guidelines A55189 - MolDX: MECP2 Genetic Testing Coding and Billing Guidelines A55190 - MolDX: Mitochondrial Nuclear Gene Tests Coding and Billing Guidelines A55191 - MolDX: MMACHC Test Coding and Billing Guidelines A55195 - MolDX: myPap™ Coding and Billing Guidelines A55197 - MolDX: Next Generation Sequencing Coding and Billing Guidelines A55198 - MolDX: NSD1 Gene Tests Coding and Billing Guidelines A55230 - MolDX: Oncotype DX® Breast Cancer Assay Billing and Coding Guidelines A55231 - MolDX: Oncotype DX® Colon Cancer Assay Update A55199 - MolDX: PAX6 Gene Sequencing Coding and Billing Guidelines A55200 - MolDX: PIK3CA Gene Tests Coding and Billing Guidelines A55201 - MolDX: PreDx® Coding and Billing Guidelines A55202 - MolDX: Progensa® PCA3 Assay Coverage Update A55203 - MolDX: PTCH1 Gene Testing Coding and Billing Guidelines A55204 - MolDx: ResponseDX Tissue of Origin® Coding and Billing Guidelines A55205 - MolDX: RPS19 Gene Tests Coding and Billing Guidelines A55206 - MolDX: SEPT9 Gene Test Coding and Billing Guidelines A55621 - MolDX: Short Tandem Repeat (STR) Markers and Chimerism (codes 81265-81268) Coding and Billing Guidelines A55207 - MolDX: SLCO1B1 Genotype Coding and Billing Guidelines A55208 - MolDX: SMPD1 Genetic Testing Coding and Billing Guidelines A55209 - MolDX: STAT3 Gene Testing Coding and Billing Guidelines A55210

- MolDX: SULT4A1 Genetic Testing Coding and Billing Guidelines A55211 - MolDX: TERC Gene Tests Coding and Billing Guidelines A55221 - MolDX: TP53 Gene Test Coding and Billing Guidelines A55222 - MolDX: UGT1A1 Gene Analysis Coding and Billing Guidelines A55223 - MolDX: Vectra™ DA Coding and Billing Guidelines A55232 - MolDX: VEGFR2 Tests Coding and Billing Guidelines A55391 - Response to Comments: MolDX: Molecular Diagnostic Tests (MDT) (L36807)

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 Back to Top

Keywords

N/A Read the **LCD Disclaimer** Back to Top