LCD - MolDX: Molecular Diagnostic Tests (MDT) (L36256)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
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

LCD Information

Document Information

LCD ID

L36256

LCD Title

MolDX: Molecular Diagnostic Tests (MDT)

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

Proposed LCD in Comment Period
N/A

Source Proposed LCD
N/A

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

Revision Effective Date
For services performed on or after 05/04/2023

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
08/16/2015

Notice Period End Date
09/30/2015

Issue

Issue Description

This LCD outlines limited coverage for this service with specific details under **Coverage Indications, Limitations and/or Medical Necessity.**

CMS National Coverage Policy

Title XVIII of the Social Security Act, §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, §1862(a)(1)(D), Investigational or Experimental.

45 CFR §162.1002 (a)(5), Medical data code sets

CMS Internet-Only Manual, Pub. 100-08, Medicare Program Integrity Manual, Chapter 13, §13.5.4 Reasonable and Necessary Provisions in LCDs

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 codes from a code set recognized in 45 CFR §162.1002(a)(5), and termed "HIPAA compliant code sets" throughout the remainder of this LCD.
• lists specific covered tests that have completed the registration and TA process and meet 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?

Molecular Diagnostic Test (MDT) Policy Specific Definitions

MDT: Any test that involves the detection or identification of nucleic acid(s) deoxyribonucleic acid/ribonucleic acid (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.

Laboratory developed test (LDT): Any test developed by a laboratory developed without Food and Drug Administration (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 code from a HIPAA compliant code set 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 a Not Otherwise Classified (NOC) code

Unique Test Identifier Requirement

Because the available language in the current HIPAA compliant code sets used 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 receive 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.

Technology Assessments (TA)

Molecular Diagnostic Services Program (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 addressed by separate Noridian policy. In addition, the CPT codes listed under Group 1 are addressed in the MolDX® program. If a test is not linked below under Related Local Coverage Documents, it may be addressed 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.

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

General Information

Associated Information

N/A

Sources of Information

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	REASONS FOR CHANGE
05/04/2023	R15	Under **CMS National Coverage Policy** deleted regulation Pub 100-08 PIM, Ch. 13, Sec 13.1.3, Program Integrity Manual, and added CMS Internet-Only Manual, Pub. 100-8, Medicare Program Integrity Manual, Chapter 13, §13.5.4 Reasonable and Necessary Provisions in LCDs. Formatting, punctuation and typographical errors were corrected throughout the LCD. Acronyms were inserted where appropriate throughout the LCD.	• Provider Education/Guidance
11/01/2019	R14	The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD. 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.	• Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.)
11/01/2019	R13	Under **CMS National Coverage Policy** added regulation 45 CFR §162.1002 (a)(5). Under **Coverage Indications, Limitations and/or Medical Necessity** changed the third bullet to read, "defines the payment rules applied to covered tests that are not reported with specific codes from a code set recognized in 45 CFR §162.1002 (a)(5), and termed "HIPAA compliant code sets" throughout the remainder of this LCD". Under **Applicable Tests/Assays** subheading changed verbiage under the third bullet to read, "All tests/assays billed with more than one code from a HIPAA compliant code set to identify the service, including combinations of method-based, serology-based, and anatomic pathology codes". Under **Unique Test Identifier Requirement** subheading	• Provider Education/Guidance

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		changed verbiage in the first two sentences to read, "Because the available language in the current HIPAA compliant code sets used 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 receive an identifier specific to the applicable test and submit the test assigned identifier with the claim for reimbursement" and deleted the verbiage, "Laboratory providers who bill MDT services must register test services on the DEX Diagnostics Exchange". Under **Covered Tests** subheading deleted the verbiage, "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". 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.	
11/01/2019	R12	11/01/2019: This LCD is being revised in order to adhere to CMS requirements per Chapter 13, Section 13.5.1 of the Program Integrity Manual. There has been no change in coverage with this LCD revision. Regulations regarding billing and coding were removed from the **CMS National Coverage Policy** section of this LCD and placed in the related Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) A57627 article. *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.*	• Provider Education/Guidance
11/01/2019	R11	As required by CR 10901, all billing and coding information has been moved to the companion article, this article is	• Revisions Due To Code Removal

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		linked to the LCD. 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.	
11/01/2019	R10	As required by CR 10901, all billing and coding information has been moved to the companion article, this article is linked to the LCD. 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 • Revisions Due To CPT/HCPCS Code Changes
01/01/2019	R9	01/23/2019 - Either the short and/or long code description was changed for the following code(s). **Please Note:** Depending on which descriptor was used, there may not be any changes to the code display in this document: 0008U descriptor was changed in Group 1 0011M descriptor was changed in Group 1	• Creation of Uniform LCDs With Other MAC Jurisdiction • Revisions Due To CPT/HCPCS Code Changes
01/01/2019	R8	The following paragraph under Covered Tests has been clarified: **Other tests/assays may be addressed by separate Noridian policy. In addition the CPT codes listed under Group 1 are addressed in the MolDX program. If a test is not linked below under Related Local Coverage Documents, it may be addressed 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.**	• Other (Clarification of paragraph requested by the MolDX contractor.)
01/01/2019	R7	Corrected typographical error in R7 revision history: CPT codes 71178, 71179, 71180 should be 81178, 81179 and 81180.	• Typographical Error

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
01/01/2019	R6	The following updates were made as a result of the 2019 Annual HCPCS code update: Deleted codes:0001M, 81211, 81213, 81214 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 Codes with descriptor changes: 0006U, 0012M, 0031U, 0032U, 81109, 81162, 81212, 81215, 81216, 81217, 81244, 81287, 81327, 81334	• Creation of Uniform LCDs With Other MAC Jurisdiction • Revisions Due To CPT/HCPCS Code Changes
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.	• Creation of Uniform LCDs With Other MAC Jurisdiction • Revisions Due To CPT/HCPCS Code Changes
01/01/2018	R4	Removed G0452, 88380, 88381 because they no longer require a DEX Z code identifier. Revised the link for technical assessment information. 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	• Creation of Uniform

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		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. 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.	LCDs With Other MAC Jurisdiction • Revisions Due To CPT/HCPCS Code Changes
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	• Creation of Uniform LCDs With Other MAC Jurisdiction

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		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.	

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

A54505 - (MCD Archive Site)
A55712 - Billing and Coding: MolDX: Abbott RealTime IDH1 and IDH2 testing for Acute Myeloid Leukemia (AML)
A54358 - Billing and Coding: MolDX: Afirma™ Assay by Veracyte
A54388 - Billing and Coding: MolDX: bioTheranostics Cancer TYPE ID®
A54420 - Billing and Coding: MolDX: FDA-Approved BRAF Tests
A54424 - Billing and Coding: MolDX: FDA-Approved EGFR Tests
A54500 - Billing and Coding: MolDX: FDA-Approved KRAS Tests
A55295 - Billing and Coding: MolDX: Germline testing for use of PARP inhibitors
A54447 - Billing and Coding: MolDX: MammaPrint
A57527 - Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT)
A54482 - Billing and Coding: MolDX: Oncotype DX® Breast Cancer Assay
A54486 - Billing and Coding: MolDX: Oncotype DX® Colon Cancer
A55888 - Billing and Coding: MolDX: ThermoFisher Oncomine Dx Target Test For Non-Small Cell Lung Cancer
A54554 - Response to Comments: MolDX: Molecular Diagnostic Tests (MDT)

Related National Coverage Documents

N/A

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
05/03/2023	05/04/2023 - N/A	Currently in Effect (This Version)
01/29/2020	11/01/2019 - 05/03/2023	Superseded
01/23/2020	11/01/2019 - N/A	Superseded
12/04/2019	11/01/2019 - N/A	Superseded
10/17/2019	11/01/2019 - N/A	Superseded
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.		

Keywords

N/A