FUTURE Local Coverage Determination (LCD):
Molecular Diagnostic Tests (MDT) (L33541)

Please note: Future Effective Date.

Contractor Information
Contractor Name
Noridian Administrative Services, LLC opens in new window
Contract Number
01112
Contract Type
MAC - Part B

LCD Information
Document Information

LCD ID
L33541

LCD Title
Molecular Diagnostic Tests (MDT)

Jurisdiction opens in new window
California - Northern

Original Effective Date
For services performed on or after 09/16/2013

Revision Effective Date
For services performed on or after 09/16/2013

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
N/A

Notice Period End Date
N/A

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.
Coverage Guidance

**Coverage Indications, Limitations, and/or Medical Necessity**

As of September 16, 2013 Noridian accepts all coverage determinations made by Palmetto GBA through the MolDX Program, which are discussed in the details of this policy.

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 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?

**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**

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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 with the following methods:
- Z-Code Identifier Application
- Palmetto GBA Test Identifier (PTI) Application.

Technology Assessments (TA)
Noridian agrees that all test/assay clinical information will be reviewed through the MolDX Program 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. Noridian and the MolDX Program will only cover and reimburse tests that demonstrate analytical and clinical validity, and clinical utility. Prior to this TA and published coverage determination, Noridian and the MolDX Program will consider all tests as noncovered services.

Payment Rules
Noridian will apply the following payment rules established by the MolDX Program:
- Tests submitted and paid that have NOT been reviewed and approved through the process outlined in this policy will be non-covered.
- Approved tests will be 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 specific coding and billing information.

The following tests have completed the MolDX Program application review and/or technical assessment and meet Medicare reasonable and necessary criteria:

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Test Developer</th>
<th>Test ID</th>
<th>CPT Code(s)</th>
<th>Publish Date</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Afirma™</td>
<td>Veracyte</td>
<td>ZB846</td>
<td>84999</td>
<td>10/31/12</td>
<td>01/01/12</td>
</tr>
<tr>
<td>Allomap</td>
<td>Expression Diagnostics</td>
<td>ZB863</td>
<td>86849</td>
<td>10/31/12</td>
<td>2/28/12*</td>
</tr>
<tr>
<td>Avise PG</td>
<td>Exagen Diagnostics, Inc.</td>
<td>PBD31</td>
<td>84999</td>
<td>10/31/12</td>
<td>04/25/12</td>
</tr>
<tr>
<td>Cancer TYPE ID</td>
<td>bioTheranostics</td>
<td>PBU00</td>
<td>84999</td>
<td>10/31/12</td>
<td>07/25/11*</td>
</tr>
<tr>
<td>cobas® 4800 BRAF V600</td>
<td>Roche</td>
<td>ZB794</td>
<td>84999</td>
<td>10/31/12</td>
<td>09/07/12</td>
</tr>
<tr>
<td>Corus® CAD</td>
<td>CardioDx, Inc.</td>
<td>ZB854</td>
<td>84999</td>
<td>10/31/12</td>
<td>01/01/12</td>
</tr>
<tr>
<td>HERmark®</td>
<td>Monogram</td>
<td>PB839</td>
<td>84999</td>
<td>10/31/12</td>
<td>12/09/11</td>
</tr>
<tr>
<td>MammaPrint™</td>
<td>Agendia</td>
<td>PB864</td>
<td>84999</td>
<td>10/31/12</td>
<td>11/16/09*</td>
</tr>
<tr>
<td>Oncotype DX® Breast</td>
<td>Genomic Health</td>
<td>PR008</td>
<td>84999</td>
<td>10/31/12</td>
<td>09/02/08*</td>
</tr>
<tr>
<td>Oncotype DX® Colon</td>
<td>Genomic Health</td>
<td>PR861</td>
<td>84999</td>
<td>10/31/12</td>
<td>03/26/12</td>
</tr>
<tr>
<td>Progensa® PCA3</td>
<td>Gen-Probe Incorporated</td>
<td>ZBA41</td>
<td>84999</td>
<td>10/31/12</td>
<td>05/07/12</td>
</tr>
<tr>
<td>therscreen</td>
<td>Qiagen</td>
<td>ZBT98</td>
<td>81479</td>
<td>04/30/13</td>
<td>04/30/13</td>
</tr>
<tr>
<td>Tissue of Origin</td>
<td>Pathworks</td>
<td>ZB798</td>
<td>84999</td>
<td>10/31/12</td>
<td>07/25/11*</td>
</tr>
<tr>
<td>Vectra™ DA</td>
<td>Crescendo</td>
<td>ZBC85</td>
<td>84999</td>
<td>5/10/13</td>
<td>06/30/12</td>
</tr>
<tr>
<td>Vysis</td>
<td>Abbot</td>
<td>ZB976</td>
<td></td>
<td>04/29/13</td>
<td>08/27/11</td>
</tr>
</tbody>
</table>

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To obtain a unique identifier for a test, to request a technical assessment, or for additional MolDX Program information, go to the Medicare home page @PalmettoGBA.com/MolDX.

Both Noridian and Palmetto GBA expect laboratory providers to follow test indications published by the developer.

**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.

999x Not Applicable

**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:** The following code included in the April release will be published in text until the annual CPT update:

81161 - DMD Dup/Delet Analysis

DMD (dystrophin) (eg, Duchene/Becker muscular dystrophy) deletion analysis, and duplication analysis.

**Group 1 Codes:**

- 81200 - 81383 opens in new window Aspa gene - Hla ii typing 1 allele hr
- 81400 - 81479 opens in new window Mopath procedure level 1 - Unlisted molecular pathology
- 84999
- 85999
- 86849
- 87999
- 88199
- 88299

Clinical chemistry test
Hematology procedure
Immunology procedure
Microbiology procedure
Cytopathology procedure
Cytogenetic study

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ICD-9 Codes that Support Medical Necessity

**Group 1 Paragraph:** N/A

**Group 1 Codes:**
xx000  Not Applicable

ICD-9 Codes that DO NOT Support Medical Necessity
N/A

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**General Information**

**[FUTURE]**

Associated Information
N/A

Sources of Information and Basis for Decision

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**Revision History Information**

Please note: The Revision History information included in this LCD prior to 1/24/2013 will now display with a Revision History Number of "R1" at the bottom of this table. All new Revision History information entries completed on or after 1/24/2013 will display as a row in the Revision History section of the LCD and numbering will begin with "R2".

<table>
<thead>
<tr>
<th>Revision History Date</th>
<th>Revision History Number</th>
<th>Revision History Explanation</th>
<th>Reason(s) for Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/16/2013</td>
<td>R1</td>
<td>Multiple verbiage changes in the Coverage Indications, Limitations and/or Medical Necessity section were made in conjunction with Palmetto GBA. The following effective dates in the table were changed: Afirma Assay by Veracyte was changed to 01/01/12, HERmark by Monogram was changed to 12/09/11, Vectra DA by Crescendo was changed to 06/30/12 and Vysis by Abbot was changed to 08/27/2011 after confirmation with Palmetto GBA.</td>
<td>• Creation of Uniform LCDs With Other MAC Jurisdiction</td>
</tr>
</tbody>
</table>

Providers are referred to the Palmetto website www.palmettogba.com/MolDX for specific coding and billing information.

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