Local Coverage Determination (LCD):
MolDX: Circulating Tumor Cell Marker Assays (L35071)

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Contractor Information

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<tr>
<th>Contractor Name</th>
<th>Contract Type</th>
<th>Contract Number</th>
<th>Jurisdiction</th>
<th>State(s)</th>
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<tr>
<td>Palmetto GBA</td>
<td>A and B MAC</td>
<td>10112 - MAC B</td>
<td>J - J</td>
<td>Alabama</td>
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<td>Virginia</td>
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<td>11502 - MAC B</td>
<td>J - M</td>
<td>North Carolina</td>
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LCD Information

Document Information

LCD ID
L35071

Original ICD-9 LCD ID
L34631

LCD Title
MolDX: Circulating Tumor Cell Marker Assays

Proposed LCD in Comment Period
N/A

Source Proposed LCD
N/A

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CMS National Coverage Policy
Title XVIII of the Social Security Act, §1862(a)(1)(A). Allows coverage and payment for only those services that are considered to be reasonable and necessary.

Title XVIII of the Social Security Act, §1833(e). Prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

42 CFR 410.32(a). Order diagnostic tests.

42 CFR 411.15(k)(1). Particular Services excluded from coverage.

CMS Internet-Only Manuals, Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, §§ 80.1, Clinical Laboratory services.

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

This is a NON-coverage policy for all circulating tumor cells (CTC) assays, including but not limited to CellSearch (Veridex), OncoCEE (Biocept) and PCR (RT-PCR) assays.

Palmetto GBA has had limited coverage for the Veridex CTC assay for breast, colon and prostate cancer. Although the detection of elevated CTCs during therapy is a definitive indication of subsequent rapid disease progression and mortality in breast, colorectal and prostate cancer, no data subsequent to Palmetto GBA's limited coverage policy (L31703) has been forthcoming to demonstrate improved patient outcomes, or that the assay changes physician management to demonstrate improved patient outcomes.

Consequently, CTC testing for all malignant diagnoses will be denied as not reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A).

Summary of Evidence

N/A

Analysis of Evidence (Rationale for Determination)

N/A
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:

86152  CELL ENUMERATION USING IMMUNOLOGIC SELECTION AND IDENTIFICATION IN FLUID SPECIMEN (EG, CIRCULATING TUMOR CELLS IN BLOOD);

86153  CELL ENUMERATION USING IMMUNOLOGIC SELECTION AND IDENTIFICATION IN FLUID SPECIMEN (EG, CIRCULATING TUMOR CELLS IN BLOOD); PHYSICIAN INTERPRETATION AND REPORT, WHEN REQUIRED

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph: N/A

ICD-10 Codes Description

XX000    Not Applicable

ICD-10 Codes that DO NOT Support Medical Necessity N/A

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General Information

Associated Information

N/A

Sources of Information


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Bibliography
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Revision History Information

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<th>Revision History Date</th>
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<th>Revision History Explanation</th>
<th>Reason(s) for Change</th>
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<tbody>
<tr>
<td>02/26/2018</td>
<td>R4</td>
<td>The Jurisdiction &quot;J&quot; Part B Contracts for Alabama (10112), Georgia (10212) and Tennessee (10312) are now being serviced by Palmetto GBA. The notice period for this LCD begins on 12/14/17 and ends on 02/25/18. Effective 02/26/18, these three contract numbers are being added to this LCD. No coverage, coding or other substantive changes (beyond the addition of the 3 Part B contract numbers) have been completed in this revision. Added MolDX: into the title of the policy.</td>
<td>Change in Affiliated Contract Numbers</td>
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<tr>
<td>07/20/2017</td>
<td>R3</td>
<td>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.</td>
<td>Typographical Error</td>
</tr>
<tr>
<td>10/01/2015</td>
<td>R2</td>
<td>Annual review completed. Under the CMS National Coverage Policy section, corrected the chapter referenced for the Medicare Benefit Policy Manual from Chapter 12 to Chapter 15.</td>
<td>Other (Annual Validation)</td>
</tr>
<tr>
<td>10/01/2015</td>
<td>R1</td>
<td>Corrected a typographical error in the CMS National Coverage Policy section.</td>
<td>Typographical Error</td>
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Associated Documents
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