Local Coverage Determination for MolDX: Circulating Tumor Cell Markers (L35710)

**Contractor Information**

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<th>CONTRACTOR NAME</th>
<th>CONTRACT TYPE</th>
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<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC 01111 - MAC A J - E</td>
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<td>Noridian Healthcare Solutions, LLC</td>
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**LCD Information**

**Document Information**

- **LCD ID**: L35710
- **Original ICD-9 LCD ID**: L35217
- **LCD Title**: MolDX: Circulating Tumor Cell Marker Assays
- **Proposed LCD in Comment Period**

- **Original Effective Date**: For services performed on or after 10/01/2015
- **Revision Effective Date**: For services performed on or after 10/01/2017
- **Revision Ending Date**: N/A

Local Coverage Determination for MolDX: Circulating Tumor Cell Mark...

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 the circulating tumor cell (CTC) assay, including but not limited to the CellSearch (Veridex), OnoCEE (Biocept) and PCR (RTPCR) Assays.

CTCs are found in the serum during the metastatic process of solid tumors when cells from a primary tumor invade, detach, disseminate, colonize and proliferate to a distant site. The detection of elevated CTCs during therapy is an indication of disease progression and overall survival in some cancers, however the medical literature does not demonstrate the test findings contribute to an improvement in patient outcomes. Adoption of the test into treatment paradigms and clinical guidelines has not occurred. CTC testing for all malignant diagnoses will be denied as not reasonable and necessary.

Summary of Evidence

NA

Analysis of Evidence

(Rationale for Determination)
- 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:
N/A

Group 1 Codes:

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<td>86152</td>
<td>CELL ENUMERATION USING IMMUNOLOGIC SELECTION AND IDENTIFICATION IN FLUID SPECIMEN (EG, CIRCULATING TUMOR CELLS IN BLOOD);</td>
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<tr>
<td>86153</td>
<td>CELL ENUMERATION USING IMMUNOLOGIC SELECTION AND IDENTIFICATION IN FLUID SPECIMEN (EG, CIRCULATING TUMOR CELLS IN BLOOD); PHYSICIAN INTERPRETATION AND REPORT, WHEN REQUIRED</td>
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ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph:
N/A

Group 1 Codes:

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ICD-10 Codes that DO NOT Support Medical Necessity

N/A

ICD-10 Additional Information

- General Information

Associated Information
N/A

Sources of Information
N/A

Bibliography


### 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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<td>10/01/2017</td>
<td>R2</td>
<td>Added MolDX into the title of the LCD and revised verbiage to be consistent with the MolDX Program. There is no change in coverage.</td>
<td>• Creation of Uniform LCDs With Other MAC Jurisdiction</td>
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<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>
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<td>10/01/2015</td>
<td>R1</td>
<td>This final LCD effective 10/1/2015, combines JEA L35711 into the JEB LCD so that both JEA and JEB contract numbers will have the same final MCD LCD number.</td>
<td>• Creation of Uniform LCDs Within a MAC Jurisdiction</td>
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### Associated Documents

- **Attachments**
  - N/A

- **Related Local Coverage Documents**
  - Article(s)
    - A55593 - MolDX: OncoCee™ Billing and Coding Guidelines

- **Related National Coverage Documents**
  - N/A

- **Public Version(s)**
  - Updated on 11/09/2017 with effective dates 10/01/2017 - N/A
  - Updated on 08/10/2016 with effective dates 10/01/2015 - 09/30/2017
  - Updated on 11/13/2014 with effective dates 10/01/2015 - N/A

### Keywords
- Circulating Tumor
- 86152
- 86153

Read the **LCD Disclaimer**