

**Centers for Medicare & Medicaid Services**

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## Local Coverage Determination (LCD): MolDX: Circulating Tumor Cell Marker Assays (L34066)

### - Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
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**  
L34066

**Original ICD-9 LCD ID**  
[L32528](#)

**LCD Title**

MolDX: Circulating Tumor Cell Marker Assays

**Proposed LCD in Comment Period**

N/A

**Source Proposed LCD**

N/A

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**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

**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, §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)**

NA

**- 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
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**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

**Group 1 Codes:**

ICD-10 CODES	DESCRIPTION
XX000	Not Applicable

**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

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**- Revision History Information**

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
10/01/2017	R2	<p>Added MoIDX into the title of the LCD and revised verbiage to be consistent with the MoIDX Program. There is no change in coverage.</p> <p>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.</p>	<ul style="list-style-type: none"> <li>• Creation of Uniform LCDs With Other MAC Jurisdiction</li> </ul>
10/01/2015	R1	<p>This final LCD, effective 10/1/2015, combines JFA L35096 into the JFB LCD so that both JFA and JFB contract numbers will have the same final MCD LCD.</p>	<ul style="list-style-type: none"> <li>• Creation of Uniform LCDs Within a MAC Jurisdiction</li> </ul>

– **Associated Documents**

**Attachments**

N/A

**Related Local Coverage Documents**

Article(s)

A55598 - 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 03/31/2014 with effective dates 10/01/2015 - N/A

– **Keywords**

- Circulating Tumor
- 86152
- 86153

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