## Contractor Information

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<th>CONTRACTOR NAME</th>
<th>CONTRACT TYPE</th>
<th>CONTRACT NUMBER</th>
<th>JURISDICTION</th>
<th>STATE(S)</th>
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## LCD Information

### Document Information

<table>
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<tr>
<th>LCD ID</th>
<th>Original Effective Date</th>
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L35710

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.

42 CFR 410.32(a). Order diagnostic tests.

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

**Coverage Guidance**

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

This is a **NON**-coverage policy for all circulating tumor cells (CTC) assays. This policy does not address tests for circulating free or circulating tumor DNA (cfDNA; ctDNA).

**Summary of Evidence**

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 has been forthcoming to demonstrate improved patient outcomes, or that the assay changes physician management to demonstrate improved patient outcomes.

**Analysis of Evidence**

**(Rationale for Determination)**

**Level of Evidence**

Quality of evidence – absent

Strength of evidence – absent

Weight of evidence – absent

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). There are been no substantive articles demonstrating clinical utility for this assay – prospective studies that demonstrate improved patient outcomes based on testing results, or that testing changes physician management to change patient outcomes.

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**General Information**

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Bibliography


5. Coumans FA, Ligthart ST, Uhr JW, Terstappen LW. Challenges in the enumeration and phenotyping of CTC. *Clin Cancer Res* 15, 2012 18;5711.


### Revision History Information

<table>
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<tr>
<th>REVISION HISTORY DATE</th>
<th>REVISION HISTORY NUMBER</th>
<th>REVISION HISTORY EXPLANATION</th>
<th>REASON(S) FOR CHANGE</th>
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<tr>
<td>12/01/2019</td>
<td>R5</td>
<td>The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.</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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<tr>
<td>12/01/2019</td>
<td>R4</td>
<td>As required by CR 10901, all billing and coding information has been moved to the companion article, this article is linked to the LCD.</td>
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<tr>
<td>09/24/2018</td>
<td>R3</td>
<td>Indications and limitations were corrected to clarify that this policy does not address tests for circulating free or circulating tumor DNA (cfDNA; ctDNA). Completed 21st Century Cures Act required fields.</td>
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Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.)

Revisions Due To Code Removal

Creation of Uniform LCDs With Other MAC Jurisdiction

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### REVISION HISTORY

<table>
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<tr>
<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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<tr>
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<td></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>
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<tr>
<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)

A57815 - Billing and Coding: MolDX: Circulating Tumor Cell Marker Assays
A55593 - Billing and Coding: MolDX: OncoCee™

**Related National Coverage Documents**

N/A

**Public Version(s)**

Updated on 01/28/2020 with effective dates 12/01/2019 - N/A
Updated on 11/23/2019 with effective dates 12/01/2019 - N/A
Updated on 09/27/2018 with effective dates 09/24/2018 - 11/30/2019

Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

### Keywords

- Circulating Tumor