

Local Coverage Determination (LCD): MoIDX: Circulating Tumor Cell Marker Assays (L35710)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01911 - MAC A	J - E	American Samoa California - Entire State Guam Hawaii Nevada Northern Mariana Islands

LCD Information

Document Information

LCD ID

Original Effective Date

L35710

For services performed on or after 10/01/2015

LCD Title

MoIDX: Circulating Tumor Cell Marker Assays

Revision Effective Date

For services performed on or after 12/01/2019

Proposed LCD in Comment Period

N/A

Revision Ending Date

N/A

Source Proposed LCD

N/A

Retirement Date

N/A

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Notice Period Start Date

N/A

Notice Period End Date

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.

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
12/01/2019	R5	<p>The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.</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"> Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.)
12/01/2019	R4	<p>As required by CR 10901, all billing and coding information has been moved to the companion article, this article is linked to the LCD.</p>	<ul style="list-style-type: none"> Revisions Due To Code Removal
09/24/2018	R3	<p>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.</p>	<ul style="list-style-type: none"> Creation of Uniform LCDs With Other MAC Jurisdiction

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"> • Creation of Uniform LCDs With Other MAC Jurisdiction
10/01/2015	R1	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.	<ul style="list-style-type: none"> • Creation of Uniform LCDs Within a MAC Jurisdiction

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A57815 - Billing and Coding: MoIDX: Circulating Tumor Cell Marker Assays

A55593 - Billing and Coding: MoIDX: 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

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Keywords

- Circulating Tumor