

Centers for Medicare & Medicaid Services

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

- 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

L35710

Original ICD-9 LCD ID

[L35217](#)

LCD Title

MoIDX: 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

N/A

Retirement Date

N/A

Source Proposed LCD

N/A

Notice Period Start Date

N/A

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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.

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

Bibliography

1. Budd G, Cristofanilli M, Ellis M et al. Circulating Tumor Cells Versus Imaging-Predicting Overall Survival in Metastatic Breast Cancer. *Clin Cancer Res.* 2006; 12(21):6403-6409.

2. Chan F, Goodman O, Fink L, Vogelzang NJ, Pomerantz D, Khoury JD. Dramatically Elevated Circulating Tumor Cell Numbers in a Patient With Small Cell Neuroendocrine Carcinoma of the Prostate. *Arch Pathol Lab Med.* 2010;134:120-123.
3. Cohen SJ, Punt C, Iannotti N, et al. Prognostic significance of circulating tumor cells in patients with metastatic colorectal cancer. *Annals of Oncol.* 2009;20(7):1223-1229.
4. Cohen SJ, Punt C, Iannotti N, et al. Relationship of Circulating Tumor Cells to Tumor Response, Progression-Free Survival, and Overall Survival in Patients with Metastatic Colorectal Cancer. *J Clin Oncol.* 2008;26(19):3213-3221.
5. Coumans FA, Ligthart ST, Uhr JW, Terstappen LW. Challenges in the enumeration and phenotyping of CTC. *Clin Cancer Res* 15, 2012 18:5711.
6. Cristofanilli M, Budd GT, Ellis MJ, et al. Circulating Tumor Cells, Disease Progression, and Survival in Metastatic Breast Cancer. *NEJM* 2004;351:781-91.
7. Danila DC, Heller G, Gignac GA, et al. Circulating Tumor Cell Number and Prognosis in Progressive Castration-Resistant Prostate Cancer. *Clin Cancer Res.* 2007;13(23):7053-7058.
8. Dawood S, Broglio K, Valero V, et al. Circulating Tumor Cells in Metastatic Breast Cancer From Prognostic Stratification to Modification of the Staging System? *Cancer.*2008;113(9):2422-2430.
9. de Bono JS, Scher H, Montgomery B, et al. Circulating Tumor Cells Predict Survival Benefit from Treatment in Metastatic Castration-Resistant Prostate Cancer. *Clin Cancer Res.* 2008;14(19):6302-6309.
10. De Giorgi U, Valero V, Rohren E, et al. Circulating Tumor Cells and [18F]Fluorodeoxyglucose Positron Emission Tomography/Computed Tomography for Outcome Prediction in Metastatic Breast Cancer. *J Clin Oncol.* 2009;27(20):3303-3311.
11. Denlinger CS and Cohen SJ. Progress in the Development of Prognostic and Predictive Markers for Gastrointestinal Malignancies. *Curr Treat Options Oncol.* 2007;8(5):339-351.
12. Fischer AH. Circulating Tumor Cells: Seeing is Believing. *Arch Pathol Lab Med.* 2009;133(9):1367-1369.
13. Fleisher M, Danila DC, Rathkopf D, et al. Circulating tumor cells (CTC) in patients with metastatic castration resistant prostate cancer (CRPC) receiving abiraterone acetate (AA) after failure of docetaxel-based chemotherapy. *J Clin Oncol.* 2009;27:15s (suppl; abstr 5049).
14. Goodman, Jr. OB, Fink LM, Symanowski JT, et al. Circulating Tumor Cells in Patients with Castration-Resistant Prostate Cancer Baseline Values and Correlation with Prognostic Factors. *Cancer Epidemiol Biomarkers Prev.* 2009;18(6):1904-1913.
15. Harris L, Fritsche H, Mennelet R, et al. American Society of Clinical Oncology 2007 Update of Recommendations for the Use of Tumor Markers in Breast Cancer. *J Clin Oncol.* 2007;25(33):5287-5312.
16. Hayes DF and Smerage J. Is there a Role for Circulating Tumor Cells in the Management of Breast Cancer? *Clinical Cancer Res.* 2008;14(12):3646-3650.
17. Hayes DF, Cristofanilli M, Budd GT, et al. Circulating Tumor Cells at Each Follow-up Time Point During Therapy of Metastatic Breast Cancer Patients Predict Progression-Free and Overall Survival. *Clin Cancer Res.* 2006;12(14):4218-4224.
18. Hiltermann T, Pore M, van den Berg A, et al. Circulating tumor cells in small-cell lung cancer: a predictive and prognostic factor. *Ann Oncol* 2012; 23(11):2937-42.
19. Khan MS, Kirkwood A, Tsiganiot T, et al. Circulating tumor cells as prognostic markers in neuroendocrine tumors. *JCO* 10.1200/JCO.2012.44.2905.
20. Okegawa T, Nutahara K, Higashihara E. Prognostic Significance of Circulating Tumor Cells in Patients with Hormone Refractory Prostate Cancer. *J of Urology.* 2009; 181: 1091-1097.
21. Olmos D, Arkenau HT, Ang JE, et al. Circulating tumour cell (CTC) counts as intermediate end points in castration-resistant prostate cancer (CRPC): a single-centre experience. *Annals of Oncol.* 2009;20(1):27-33.
22. Petrelli P, Winer E, Brahmeret J et al. Clinical Cancer Advances 2009: Major Research Advances in Cancer Treatment, Prevention, and Screening-A Report From the American Society of Clinical Oncology. *Jour of Clin Oncol.* 2009;27(35):6052-6069.
23. Sabbath KD and Schwartzberg L. Circulating Tumor Cells: Ready for Prime Time. *Commun Oncol.* 2008;5:516-520,524.
24. Scher H, Jia X, de Bono J, et al. Circulating tumour cells as prognostic markers in progressive, castration-resistant prostate cancer: a reanalysis of IMMC38 trial data. *Lancet Oncol.* 2009;10:233-239.

25. Shaffer DR, Leversha MA, Danila DC, et al. Circulating Tumor Cell Analysis in Patients with Progressive Castration-Resistant Prostate Cancer. Clin Cancer Res. 2007; 13(7):2023-2029.
26. Sieuwerts AM, Kraan J, Bolt J, et al. Anti-Epithelial Cell Adhesion Molecule Antibodies and the Detection of Circulating Normal-Like Breast Tumor Cells. J Natl Cancer Inst. 2009; 101(1): 61-66.
27. Smerage JB and Hayes DF. The Measurement and Therapeutic Implications of Circulating Tumour Cells in Breast Cancer. British Journal of Cancer. 2006; 94(1):8-12.
28. Tol J, Koopman M, Cats A, et al. Chemotherapy, Bevacizumab, and Cetuximab in Metastatic Colorectal Cancer. NEJM. 2009; 360(6):563-572.

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

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- Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)
 A55593 - MoIDX: 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

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