

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

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

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 Effective Date

For services performed on or after 10/01/2015

LCD Title**Revision Effective Date**

MoIDX: Circulating Tumor Cell Marker Assays

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

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

CPT codes, descriptions and other data only are copyright 2019 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply.

Notice Period Start Date

N/A

Notice Period End Date

N/A

Current Dental Terminology © 2019 American Dental Association. All rights reserved.

Copyright © 2019, the American Hospital Association, Chicago, Illinois. Reproduced with permission. No portion of the AHA copyrighted materials contained within this publication may be copied without the express written consent of the AHA. AHA copyrighted materials including the UB-04 codes and descriptions may not be removed, copied, or utilized within any software, product, service, solution or derivative work without the written consent of the AHA. If an entity wishes to utilize any AHA materials, please contact the AHA at 312-893-6816. Making copies or utilizing the content of the UB-04 Manual, including the codes and/or descriptions, for internal purposes, resale and/or to be used in any product or publication; creating any modified or derivative work of the UB-04 Manual and/or codes and descriptions; and/or making any commercial use of UB-04 Manual or any portion thereof, including the codes and/or descriptions, is only authorized with an express license from the American Hospital Association. To license the electronic data file of UB-04 Data Specifications, contact Tim Carlson at (312) 893-6816 or Laryssa Marshall at (312) 893-6814. You may also contact us at ub04@healthforum.com.

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

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, Tsiganiet 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
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 JFA L35096 into the JFB LCD so that both JFA and JFB contract numbers will have the same final MCD LCD.	<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)

A57816 - Billing and Coding: MoIDX: Circulating Tumor Cell Marker Assays

A55598 - Billing and Coding: MoIDX: OncoCee™

Related National Coverage Documents

N/A

Public Version(s)

Updated on 01/29/2020 with effective dates 12/01/2019 - N/A

Updated on 11/24/2019 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