

LCD Reference Article	Billing and Coding Article
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Article - Billing and Coding: MoIDX: Microsatellite Instability-High (MSI-H) and Mismatch Repair Deficient (dMMR) Biomarker for Patients with Unresectable or Metastatic Solid Tumors (A56104)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
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
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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
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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
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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

Article Information

General Information

Article ID

A56104

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

Article Title

Billing and Coding: MoIDX: Microsatellite Instability-High (MSI-H) and Mismatch Repair Deficient (dMMR) Biomarker for Patients with Unresectable or Metastatic Solid Tumors

Article Type

Billing and Coding

Original Effective Date

10/13/2018

Revision Effective Date

01/01/2024

Revision Ending Date

N/A

Retirement Date

N/A

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CMS National Coverage Policy

N/A

Article Guidance

Article Text

In May, 2017, the FDA granted accelerated approval for the use of Keytruda for treatment of patients with unresectable or metastatic solid tumors having either microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) biomarkers. Keytruda, a human PD-1 blocking antibody, is indicated for the treatment of metastatic melanoma, non-small cell lung cancer, recurrent or metastatic head and neck squamous cancer, advanced/metastatic urothelial cancer and classical Hodgkin's lymphoma.

This contractor will allow one of the following:

- dMMR by immunohistochemistry (IHC), **or**
- MSI by PCR, **or**
- Multi-gene NGS panel inclusive of MSI microsatellite loci, and MLH1, MSH2, MSH6 and PMS2 genes

Testing by one of the above methodologies is reasonable and necessary if testing for dMMR or MSI has not previously

been performed on the patient's tumor sample. A multi-gene NGS panel inclusive of MSI microsatellite loci and MLH1, MSH2, MSH6 and PMS2 gene is reasonable and necessary. A multi-gene NGS panel and separate MSI by PCR will be denied as not reasonable and necessary. If testing is performed by NGS, the test must be a properly designed and appropriately validated assay demonstrating 95% concordance to the reference method (MSI by PCR).

To report a dMMR service, please submit the following claim information:

- CPT code 88342 – One (1) unit of service
- CPT code 88341 – Three (3) units of service

To report a MSI service, please submit the following claim information:

- CPT code 81301 – One (1) unit of service

To report by NGS, please submit the following claim information:

- CPT code 81479 – One (1) unit of service

Coding Information

CPT/HCPCS Codes

Group 1 Paragraph:

N/A

Group 1 Codes: (3 Codes)

CODE	DESCRIPTION
81479	UNLISTED MOLECULAR PATHOLOGY PROCEDURE
88341	IMMUNOHISTOCHEMISTRY OR IMMUNOCYTOCHEMISTRY, PER SPECIMEN; EACH ADDITIONAL SINGLE ANTIBODY STAIN PROCEDURE (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
88342	IMMUNOHISTOCHEMISTRY OR IMMUNOCYTOCHEMISTRY, PER SPECIMEN; INITIAL SINGLE ANTIBODY STAIN PROCEDURE

Group 2 Paragraph:

CPT[®] codes that are also referenced in other articles.

Group 2 Codes: (1 Code)

CODE	DESCRIPTION
81301	MICROSATELLITE INSTABILITY ANALYSIS (EG, HEREDITARY NON-POLYPOSIS COLORECTAL CANCER, LYNCH SYNDROME) OF MARKERS FOR MISMATCH REPAIR DEFICIENCY (EG, BAT25, BAT26), INCLUDES COMPARISON OF NEOPLASTIC AND NORMAL TISSUE, IF PERFORMED

CPT/HCPCS Modifiers

Group 1 Paragraph:

N/A

Group 1 Codes:

N/A

ICD-10-CM Codes that Support Medical Necessity

Group 1 Paragraph:

N/A

Group 1 Codes:

N/A

ICD-10-CM Codes that DO NOT Support Medical Necessity

Group 1 Paragraph:

N/A

Group 1 Codes:

N/A

ICD-10-PCS Codes

N/A

Additional ICD-10 Information

N/A

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 article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

N/A

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 article, 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 article should be assumed to apply equally to all Revenue Codes.

N/A

Other Coding Information

Group 1 Paragraph:

N/A

Group 1 Codes:

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
01/01/2024	R5	Under CPT/HCPCS Codes Group 1: Codes the description was revised for 88341 and 88342. This revision is due to the 2024 Annual/Q1 CPT/HCPCS Code Update and is effective 1/1/2024.
11/01/2019	R4	Updated to indicate this article is an LCD Reference Article.
11/01/2019	R3	Corrected typographical error under Article Title .
11/01/2019	R2	11/01/2019: This article is being revised in order to adhere to CMS requirements per Chapter 13, Section 13.5.1 of the Program Integrity Manual. Under Article Title changed title from "MoIDX: Microsatellite Instability-High (MSI-

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		<p>H) and Mismatch Repair Deficient (dMMR) Biomarker Coding and Billing Guidelines for Patients with Unresectable or Metastatic Solid Tumors” to “Billing and Coding: MolDX: Microsatellite Instability-High (MSI-H) and Mismatch Repair Deficient (dMMR) Biomarker for Patients with Unresectable or Metastatic Solid Tumors”.</p> <p>Under Article Text deleted statement, “ICD10 – appropriate for the tumor type and location”.</p> <p>Under CPT/HCPCS Codes Group 1: Codes deleted CPT[®] code 81301.</p> <p>Under CPT/HCPCS Codes Group 2: Paragraph added verbiage, “CPT[®] codes that are also referenced in other articles”.</p> <p>Under CPT/HCPCS Group 2: Codes added CPT[®] code 81301. CPT[®] was inserted throughout the article where applicable.</p>
11/01/2019	R1	As required by CR 10901 article is converted to a formal billing and coding type article.

Associated Documents

Related Local Coverage Documents

LCDs

[L36256 - MolDX: Molecular Diagnostic Tests \(MDT\)](#)

Related National Coverage Documents

N/A

Statutory Requirements URLs

N/A

Rules and Regulations URLs

N/A

CMS Manual Explanations URLs

N/A

Other URLs

N/A

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.		
01/23/2024	01/01/2024 - N/A	Currently in Effect (This Version)
11/22/2023	11/01/2019 - 12/31/2023	Superseded
07/24/2023	11/01/2019 - N/A	Superseded
02/14/2020	11/01/2019 - N/A	Superseded
10/31/2019	11/01/2019 - N/A	Superseded

Keywords

N/A