

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

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CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
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<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	02102 - MAC B	J - F	Alaska
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	02201 - MAC A	J - F	Idaho
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	02202 - MAC B	J - F	Idaho
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	02301 - MAC A	J - F	Oregon
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	02302 - MAC B	J - F	Oregon
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	02401 - MAC A	J - F	Washington
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	02402 - MAC B	J - F	Washington
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<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	03102 - MAC B	J - F	Arizona
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<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	03202 - MAC B	J - F	Montana
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	03301 - MAC A	J - F	North Dakota
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<a href="#">Noridian Healthcare Solutions, LLC</a>	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 Billing and Coding Guidelines for Patients with Unresectable or Metastatic Solid Tumors

## Article Type

Billing and Coding

## Original Effective Date

10/13/2018

## Revision Effective Date

11/01/2019

## Revision Ending Date

N/A

## Retirement Date

N/A

## 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).

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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

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## 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

CODE	DESCRIPTION
	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

**Group 1 Medical Necessity ICD-10-CM Codes Asterisk Explanation:**

N/A

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

**Group 1 Paragraph:**

N/A

**Group 1 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
11/01/2019	R2	<p>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.</p> <p>Under <b>Article Title</b> changed title from "MoIDX: Microsatellite Instability-High (MSI-H) and Mismatch Repair Deficient (dMMR) Biomarker Coding and Billing Guidelines for Patients with Unresectable or Metastatic Solid Tumors" to "Billing and Coding: MoIDX: Microsatellite Instability-High (MSI-H) and Mismatch Repair Deficient (dMMR) Biomarker for Patients with Unresectable or Metastatic Solid Tumors".</p> <p>Under <b>Article Text</b> deleted statement, "ICD10 – appropriate for the tumor type and location".</p> <p>Under <b>CPT/HCPCS Codes Group 1: Codes</b> deleted CPT® code 81301.</p> <p>Under <b>CPT/HCPCS Codes Group 2: Paragraph</b> added verbiage, "CPT® codes that are also referenced in other articles".</p>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		Under <b>CPT/HCPCS Group 2: Codes</b> added CPT <sup>®</sup> code 81301. CPT <sup>®</sup> was inserted throughout the article where applicable.
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

[L36374 - MoIDX: Genetic Testing for Lynch Syndrome](#)

### 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
02/14/2020	11/01/2019 - N/A	Currently in Effect (This Version)
10/31/2019	11/01/2019 - N/A	Superseded

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

## Keywords

N/A