

Local Coverage Article: Billing and Coding: MoIDX: Microsatellite Instability-High (MSI-H) and Mismatch Repair Deficient (dMMR) Biomarker for Patients with Unresectable or Metastatic Solid Tumors (A56072)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Palmetto GBA	A and B MAC	10111 - MAC A	J - J	Alabama
Palmetto GBA	A and B MAC	10112 - MAC B	J - J	Alabama
Palmetto GBA	A and B MAC	10211 - MAC A	J - J	Georgia
Palmetto GBA	A and B MAC	10212 - MAC B	J - J	Georgia
Palmetto GBA	A and B MAC	10311 - MAC A	J - J	Tennessee
Palmetto GBA	A and B MAC	10312 - MAC B	J - J	Tennessee
Palmetto GBA	A and B and HHH MAC	11201 - MAC A	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11202 - MAC B	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11301 - MAC A	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11302 - MAC B	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11401 - MAC A	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11402 - MAC B	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11501 - MAC A	J - M	North Carolina
Palmetto GBA	A and B and HHH MAC	11502 - MAC B	J - M	North Carolina

Article Information

General Information

Article ID

A56072

Original Effective Date

08/03/2017

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

Revision Effective Date

11/07/2019

Revision Ending Date

N/A

Article Type

Billing and Coding

Retirement Date

N/A

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Statement

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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:

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:

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

N/A

ICD-10 Codes that Support Medical Necessity

N/A

ICD-10 Codes that DO NOT Support Medical Necessity

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 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.

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 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

Other Coding Information

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
11/07/2019	R1	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-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". Under Article Text deleted statement, "ICD10 – appropriate for the tumor type and location". Under CPT/HCPCS Codes Group 1: Codes deleted CPT [®] code 81301. Under CPT/HCPCS Codes Group 2: Paragraph added verbiage, "CPT [®] codes that are also referenced in other articles". Under CPT/HCPCS Group 2: Codes added CPT [®] code 81301. CPT [®] was inserted throughout the article where applicable.

Associated Documents

Related Local Coverage Document(s)

LCD(s)

L35024 - MoIDX: Genetic Testing for Lynch Syndrome

Related National Coverage Document(s)

N/A

Statutory Requirements URL(s)

N/A

Rules and Regulations URL(s)

N/A

CMS Manual Explanations URL(s)

N/A

Other URL(s)

N/A

Public Version(s)

Updated on 10/29/2019 with effective dates 11/07/2019 - N/A

Updated on 07/23/2018 with effective dates 08/03/2017 - N/A

Keywords

N/A