Local Coverage Article:
MolDX: Microsatellite Instability-High (MSI-H) and Mismatch Repair Deficient (dMMR) Biomarker Billing and Coding Guidelines for Patients with Unresectable or Metastatic Solid Tumors (A56103)

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

Contractor Information

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<tr>
<th>Contractor Name</th>
<th>Contract Type</th>
<th>Contract Number</th>
<th>Jurisdiction</th>
<th>State(s)</th>
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Article Information

General Information

Original Article Effective Date
10/13/2018
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

ICD10 – appropriate for the tumor type and location.

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 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

**CPT/HCPCS Codes**

**Group 1 Paragraph:** N/A

**Group 1 Codes:**

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<td>81301</td>
<td>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</td>
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<td>81479</td>
<td>UNLISTED MOLECULAR PATHOLOGY PROCEDURE</td>
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<td>88342</td>
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ICD-10 Codes that are Covered N/A
ICD-10 Codes that are Not Covered N/A

Revision History Information

N/A Related Local Coverage Document(s) N/A

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 08/16/2018 with effective dates 10/13/2018 - N/A

Keywords

- MolDx
- microsatellite
- MSI-H
- dMMR
- tumor
- biomarker
- Keytruda
- immunohistochemistry

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