

Local Coverage Article: MoIDX: FDA-Approved KRAS Tests (A54472)

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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

A54472

Original Effective Date

10/01/2015

Original ICD-9 Article ID

[A52559](#)

Revision Effective Date

02/26/2018

Article Title

MoIDX: FDA-Approved KRAS Tests

Revision Ending Date

N/A

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

CPT codes, descriptions and other data only are

Retirement Date

N/A

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Article Guidance

Article Text:

Two tests have met the FDA criteria for KRAS genetic testing:

1. Effective 7/6/2012
therascreen® KRAS to detect seven somatic mutations in the human KRAS oncogene was developed to aid in the identification of CRC patients for treatment with Erbitux® (cetuximab).
2. Effective 5/7/2015
cobas® KRAS to detect mutations in codons 12 and 13 of the KRAS gene was developed to aid in identification of CRC patients for treatment with Erbitux® (cetuximab) or Vectibix® (panitumumab).

To report an FDA approved KRAS, codon 12 and 13 test kit service, please submit the following claim information:

- Enter CPT 81275

- Enter the appropriate DEX Z-Code™ identifier adjacent to the CPT code in the comment/narrative field for the following Part B claim field/types:
 - Loop 2400 or SV101-7 for the 5010A1 837P
 - Box 19 for paper claim
- Enter the appropriate DEX Z-Code™ identifier adjacent to the CPT code in the comment/narrative field for the following Part A claim field/types:
 - Line SV202-7 for 837I electronic claim
 - Block 80 for the UB04 claim form
- Select the appropriate ICD-10-CM diagnosis.

NOTE: MoIDX will apply NPI to ID editing on FDA approved KRAS kits. All labs that submit claims for a KRAS, codon 12 and 13 test kit **MUST** register the test and confirm the **UNMODIFIED** use of the kit. Tests may be registered on the DEX™ Diagnostics Exchange: <https://app.dexzcodes.com/login>

This article reflects the FDA-approved indications on article creation date. MoIDX will allow future FDA approved and amended indications for these tests.

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 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

CPT/HCPCS Codes

N/A

ICD-10 Codes that are Covered

Group 1 Paragraph:

N/A

Group 1 Codes:

| ICD-10 CODE | DESCRIPTION |
|-------------|---|
| C77.0 | Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck |
| C77.1 | Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes |
| C77.2 | Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes |
| C77.3 | Secondary and unspecified malignant neoplasm of axilla and upper limb lymph nodes |
| C77.4 | Secondary and unspecified malignant neoplasm of inguinal and lower limb lymph nodes |
| C77.5 | Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes |
| C77.8 | Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions |
| C77.9 | Secondary and unspecified malignant neoplasm of lymph node, unspecified |
| C78.01 | Secondary malignant neoplasm of right lung |
| C78.02 | Secondary malignant neoplasm of left lung |
| C78.1 | Secondary malignant neoplasm of mediastinum |
| C78.2 | Secondary malignant neoplasm of pleura |
| C78.39 | Secondary malignant neoplasm of other respiratory organs |
| C78.4 | Secondary malignant neoplasm of small intestine |
| C78.5 | Secondary malignant neoplasm of large intestine and rectum |
| C78.6 | Secondary malignant neoplasm of retroperitoneum and peritoneum |
| C78.7 | Secondary malignant neoplasm of liver and intrahepatic bile duct |
| C78.80 | Secondary malignant neoplasm of unspecified digestive organ |
| C78.89 | Secondary malignant neoplasm of other digestive organs |
| C79.01 | Secondary malignant neoplasm of right kidney and renal pelvis |
| C79.02 | Secondary malignant neoplasm of left kidney and renal pelvis |
| C79.11 | Secondary malignant neoplasm of bladder |
| C79.19 | Secondary malignant neoplasm of other urinary organs |
| C79.2 | Secondary malignant neoplasm of skin |
| C79.31 | Secondary malignant neoplasm of brain |
| C79.32 | Secondary malignant neoplasm of cerebral meninges |
| C79.49 | Secondary malignant neoplasm of other parts of nervous system |

| ICD-10 CODE | DESCRIPTION |
|-------------|---|
| C79.51 | Secondary malignant neoplasm of bone |
| C79.52 | Secondary malignant neoplasm of bone marrow |
| C79.61 | Secondary malignant neoplasm of right ovary |
| C79.62 | Secondary malignant neoplasm of left ovary |
| C79.71 | Secondary malignant neoplasm of right adrenal gland |
| C79.72 | Secondary malignant neoplasm of left adrenal gland |
| C79.81 | Secondary malignant neoplasm of breast |
| C79.82 | Secondary malignant neoplasm of genital organs |
| C79.89 | Secondary malignant neoplasm of other specified sites |

ICD-10 Codes that are Not Covered

N/A

Revision History Information

| REVISION HISTORY DATE | REVISION HISTORY NUMBER | REVISION HISTORY EXPLANATION |
|-----------------------|-------------------------|--|
| 02/26/2018 | R10 | The Jurisdiction "J" Part B Contracts for Alabama (10112), Georgia (10212) and Tennessee (10312) are now being serviced by Palmetto GBA. The notice period for this article begins on 12/14/17 and ends on 02/25/18. Effective 02/26/18, these three contract numbers are being added to this article. No coverage, coding or other substantive changes (beyond the addition of the 3 Part B contract numbers) have been completed in this revision. |
| 01/29/2018 | R9 | The Jurisdiction "J" Part A Contracts for Alabama (10111), Georgia (10211) and Tennessee (10311) are now being serviced by Palmetto GBA. The notice period for this article begins on 12/14/17 and ends on 01/28/18. Effective 01/29/18, these three contract numbers are being added to this article. No coverage, coding or other substantive changes (beyond the addition of the 3 Part A contract numbers) have been completed in this revision. |
| 12/21/2017 | R8 | Corrected the Diagnostics Exchange Web address and name from McKesson Diagnostics Exchange to DEX TM Diagnostics Exchange. |
| 12/14/2017 | R7 | Removed modifier 22 references. |
| 12/07/2017 | R6 | Completed Annual Review. Added Part A Contract Numbers and DEX Z-Code |

| REVISION HISTORY DATE | REVISION HISTORY NUMBER | REVISION HISTORY EXPLANATION |
|-----------------------|-------------------------|---|
| | | Identifier information. |
| 02/24/2016 | R5 | Added statement that MoIDX will approve all future FDA-approved indications to the end of article. |
| 12/10/2015 | R4 | Reverted back to SV101-7 and for trade mark purposes, replaced ID/MoIDX identifier/Z-Code to read Z-Code™ Identifier |
| 11/19/2015 | R3 | Replaced SV101-7 with MID |
| 10/29/2015 | R2 | Annual review completed. No changes needed. |
| 10/01/2015 | R1 | Removed ICD-9 and ICD-10 codes from article text and added them to the ICD-9 field. Added contractor numbers 11302, 11402, 11502. |

Associated Documents

Related Local Coverage Document(s)

LCD(s)

L35025 - MoIDX: Molecular Diagnostic Tests (MDT)

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 12/14/2017 with effective dates 02/26/2018 - N/A

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

Keywords

N/A