

Article - Billing and Coding: MolDX: FDA-Approved KRAS Tests (A54500)

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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
Noridian Healthcare Solutions, LLC	A and B MAC	02301 - MAC A	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02302 - MAC B	J - F	Oregon
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
Noridian Healthcare Solutions, LLC	A and B MAC	03101 - MAC A	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03102 - MAC B	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03201 - MAC A	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03202 - MAC B	J - F	Montana
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
Noridian Healthcare Solutions, LLC	A and B MAC	03402 - MAC B	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03501 - MAC A	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03502 - MAC B	J - F	Utah
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
A54500

Article Title

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

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Article Type

Billing and Coding

Original Effective Date

10/01/2015

Revision Effective Date

03/03/2022

Revision Ending Date

N/A

Retirement Date

N/A

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CMS National Coverage Policy

Title XVIII of the Social Security Act, §1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

Article Guidance

Article Text

The following coding and billing guidance is to be used with its associated Local coverage determination.

Two tests have met the Food and Drug Administration (FDA) criteria for KRAS genetic testing:

1. Effective 7/6/2012

therascreen® KRAS to detect 7 somatic mutations in the human KRAS oncogene was developed to aid in the identification of colorectal cancer (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 or laboratory developed test (LDT) KRAS, codon 12 and 13 test kit service, please submit the following claim information:

- Enter CPT® 81275

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

NOTE: MoIDX will apply National Provider Identifier (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.dexcodes.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

CPT/HCPCS Codes

Group 1 Paragraph:

N/A

Group 1 Codes: (1 Code)

CODE	DESCRIPTION
81275	KRAS (KIRSTEN RAT SARCOMA VIRAL ONCOGENE HOMOLOG) (EG, CARCINOMA) GENE ANALYSIS; VARIANTS IN EXON 2 (EG, CODONS 12 AND 13)

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: (37 Codes)

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

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
C79.63	Secondary malignant neoplasm of bilateral ovaries
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-CM Codes that DO NOT Support Medical Necessity

Group 1 Paragraph:

N/A

Group 1 Codes:

N/A

ICD-10-PCS Codes

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
03/03/2022	R6	Under CMS National Coverage Policy added regulation, Title XVIII of the Social Security Act, §1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim. Under Article Text, revised sentence to read, "To report an FDA approved or laboratory developed test (LDT) KRAS, codon 12 and 13 test kit service, please submit the following claim information." This revision is effective on 03/03/2022.
10/01/2021	R5	Under Article Text corrected hyperlink for DEX webpage. Acronyms were defined and inserted where appropriate throughout the article. Formatting was corrected throughout the article. This revision is effective 10/1/2021. Under ICD-10 Codes that Support Medical Necessity Group 1: Codes added C79.63. This revision is due to the Annual ICD-10 update and will become effective on 10/1/2021.
11/01/2019	R4	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, to remove all coding

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		<p>from LCDs and incorporate into related Billing and Coding Articles.</p> <p>Under CPT/HCPCS Codes Group 1: Codes added CPT® code 81275.</p> <p>CPT® was inserted throughout the article where applicable.</p>
11/01/2019	R3	As required by CR 10901 article is converted to a formal billing and coding type article. There is no change in coverage.
12/14/2017	R2	<p>Article is updated to remove modifier 22 instruction, add Part A claim filing instructions and correct reference to and website address for DEX™ Diagnostics Exchange.</p> <p>Article number A54501 for Jurisdiction F Part A (JFA) was retired on January 24, 2018, and combined into Jurisdiction F Part B (JFB) article number A54500. JFA and JFB contract numbers will have the same final MCD article number.</p>
01/01/2016	R1	Article is revised to change the title from "MoIDX: thescreen® KRAS PCR Kit Billing/Coding Guidelines" to "MoIDX: FDA-Approved KRAS" Tests and the following diagnoses were removed to be consistent with the MoIDX Contractor coverage article: C78.00, C78.30, C79.00, C79.10, C79.40, C79.60, C79.70 and C79.9.

Associated Documents

Related Local Coverage Documents

LCDs

[L36256 - MoIDX: 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
02/28/2022	03/03/2022 - N/A	Currently in Effect (This Version)
09/03/2021	10/01/2021 - 03/02/2022	Superseded
12/04/2019	11/01/2019 - 09/30/2021	Superseded
10/16/2019	11/01/2019 - N/A	Superseded

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Keywords

N/A