LCD Reference Article	Billing and Coding Article

Article - Billing and Coding: MolDX: FDA-Approved EGFR Tests (A54424)

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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
A54424

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

Article Title
Billing and Coding: MolDX: FDA-Approved EGFR Tests

Article Type
Billing and Coding

Original Effective Date
10/01/2015

Revision Effective Date
05/30/2024

Revision Ending Date
N/A

Retirement Date
N/A

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

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

1. Effective 6/01/16

cobas EGFR Mutation Test is a real-time PCR test for the qualitative detection of defined mutations of the epidermal growth factor receptor (EGFR) gene in non-small cell lung cancer (NSCLC) patients. Defined EGFR mutations are detected using DNA isolated from formalin-fixed paraffin-embedded tumor tissue (FFPET) or circulating-free tumor DNA (cfDNA) from plasma derived from EDTA anti-coagulated peripheral whole blood.

The test is indicated as a companion diagnostic to aid in selecting NSCLC patients for treatment with the targeted therapies listed in the Table below in accordance with the approved therapeutic product labeling:

Drug	FFPET	Plasma
TARCEVA®(erlotinib)	Exon 19	Exon 19

	deletions and L858R	deletions and L858R
TAGRISSO™ (osimertinib)	T790M	

Patients with positive cobas® EGFR Mutation Test v2 test results using plasma specimens for the presence of EGFR exon 19 deletions or L858R mutations are eligible for treatment with TARCEVA® (erlotinib). Patients who are negative for these mutations by this test should be reflexed to routine biopsy and testing for EGFR mutations with the FFPET sample type.

2. Effective 7/12/13

therascreen EGFR RGQ PCR kit for the detection of the epidermal growth factor receptor (EGFR) gene for non-small cell lung cancer (NSCLC) tumor tissue to help select patients with NSCLC for whom GILOTRIF™ (afatinib), an EGFR tyrosine kinase inhibitor (TKI), is indicated.

To report an FDA approved or laboratory developed test (LDT) EGFR test kit service, please submit the following claim information:

- CPT® code: 81235
- 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
  - Item 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
- ICD-10-CM codes

NOTE: MolDX will apply NPI to ID editing on FDA approved EGFR kits. All labs that submit claims for an EGFR kit **MUST** register the test and confirm the **UNMODIFIED** use of the kit.

This article reflects the FDA-approved indications on article creation date. MolDX 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
81235	EGFR (EPIDERMAL GROWTH FACTOR RECEPTOR) (EG, NON-SMALL CELL LUNG CANCER) GENE ANALYSIS, COMMON VARIANTS (EG, EXON 19 LREA DELETION,

CODE	DESCRIPTION
	L858R, T790M, G719A, G719S, L861Q)

CPT/HCPCS Modifiers

Group 1 Paragraph:

N/A

Group 1 Codes:

N/A

ICD-10-CM Codes that Support Medical Necessity

Group 1 Paragraph:

81235

Group 1 Codes: (12 Codes)

CODE	DESCRIPTION
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung

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
05/30/2024	R6	Under **Article Text** revised 2nd and 5th bullets to remove "DEX Z-Code™" and replaced with "DEX Z-Code®". Under **ICD-10 Codes that Support Medical Necessity Group 1: Codes** added C34.00, C34.01, and C34.02. Formatting was corrected throughout the article.
03/03/2022	R5	Updated to indicate this article is an LCD Reference Article.
03/03/2022	R4	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 number 2, revised sentence to read, "To report an FDA approved or laboratory developed test (LDT) EGFR test kit service, please submit the following claim information." This revision is effective on 03/03/2022.
11/01/2019	R3	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 from LCDs and incorporate into related Billing and Coding Articles. Under **Article Text** created another bullet for verbiage, "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". Under **CPT/HCPCS Codes Group 1: Codes** added CPT® code 81235. Formatting, punctuation and typographical errors were corrected throughout the Article. CPT® was inserted throughout the article where applicable.
11/01/2019	R2	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	R1	Article is updated for consistency with the MolDX Contractor: The entire section for cobas EGFR Mutation Test was revised, including effective date; modifier 22 instruction was removed; added Part A claim filing instructions and correct reference to and website address for DEX™ Diagnostics Exchange. Article number A54423 for Jurisdiction F Part A (JFA) was retired on January 24, 2018, and combined into Jurisdiction F Part B (JFB) article number A54424. JFA and JFB contract numbers will have the same final MCD article number.

Associated Documents

Related Local Coverage Documents

LCDs

L36256 - MolDX: 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
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.		
05/24/2024	05/30/2024 - N/A	Currently in Effect (This Version)
11/22/2023	03/03/2022 - 05/29/2024	Superseded
02/28/2022	03/03/2022 - N/A	Superseded

Keywords

N/A