Local Coverage Article:
MolDX: FDA-Approved EGFR Tests (A54021)

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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
A54021

Article Title
MolDX: FDA-Approved EGFR Tests

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

Original Effective Date
10/01/2015

Revision Effective Date
02/26/2018

Revision Ending Date
N/A

Retirement Date
N/A

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 deletions and L858R	Exon 19 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 EGFR test kit service, please submit the following claim information:

- CPT code: 81235Enter the appropriate DEX Z-Code™ identifier adjacent to the CPT code inin 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
- 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

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
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

ICD-10 CODE	DESCRIPTION
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 Codes that are Not Covered

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
02/26/2018	R9	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	R8	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.
12/14/2017	R7	Removed 22 modified references and McKesson Diagnostics Exchange reference. Corrected bulleting issues.
01/26/2017	R6	Annual review completed, updated article with 2016 info, part a clm submission instructions and added new trademark for McKesson Z-code ID.
02/24/2016	R5	Added statement that MolDX will approve all future FDA-approved indications to the end of article.
01/14/2016	R4	Annual review completed, no changes needed.
12/10/2015	R3	Reverted back to SV101-7 and for trade mark purposes, replaced ID/MolDX identifier/Z-Code to read Z-Code™ Identifier
11/19/2015	R2	Replaced SV101-7 with MID, and removed 2014 coding references
10/01/2015	R1	Removed ICD-9 and ICD-10 codes from the article text.

Associated Documents

Related Local Coverage Document(s)

LCD(s)
L35025 - MolDX: 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