Local Coverage Article:
MolDX: ThermoFisher Oncomine Dx Target Test For Non-Small Cell Lung Cancer, Coding and Billing Guidelines (A55822)

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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
A55822

Article Title
MolDX: ThermoFisher Oncomine Dx Target Test For Non-Small Cell Lung Cancer, Coding and Billing Guidelines

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

Original Effective Date
12/07/2017

Revision Effective Date
07/05/2018

Revision Ending Date
N/A

Retirement Date
N/A

Article Guidance

Article Text:

The Oncomine Dx Target Test (Thermo Fisher Scientific, Inc., Waltham, MA) is a 23 gene panel including 3 gene targets approved by the FDA for non-small cell lung cancer from tissue specimens1. The test can simultaneously identify three gene variants that are key to targeted therapy selection: EGFR, BRAF and ROS1.

Gene	Variant	Targeted therapy
BRAF	BRAF V600E	TAFINLAR®(dabrafenib) in combination with MEKINIST® (trametinib)
ROS1	ROS1 fusions	XALKORI® (crizotinib)
EGFR	L858R, Exon 19 deletions	IRESSA® (gefitinib)

Erlotinib, gefitinib, or afatinib are approved therapies for NSCLC patients with EGFR exon 19 deletions and L858R mutation. The OncomineTM Dx Target is an FDA-approved companion diagnostic test for gefitinib only.

Crizotinib is very effective for NSCLC patients with ROS1 rearrangements. Oncomine DX Target Test is the only FDA approved companion diagnostic test that detects ROS1 fusions. The assay does not detect ALK fusions.

Dabrafenib in combination with Trametinib is approved therapy for NSCLC patients with a BRAF V600E mutation. Oncomine DX Target Test is the only FDA approved companion diagnostic test that detects BRAF V600E.

To report a Oncomine Dx Target Test service on tissue specimens, effective 6/22/2017, submit the following claim information:

- Select PLA 0022U for claims on of after 10/1/2017;
- Enter 1 unit of service (UOS);
- 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 for
- Select the appropriate ICD-10-CM code

https://www.accessdata.fda.gov/cdrh_docs/pdf16/p160045d.pdf

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

Group 1 Paragraph:

N/A

Group 1 Codes:

CODE	DESCRIPTION
0022U	TARGETED GENOMIC SEQUENCE ANALYSIS PANEL, NON-SMALL CELL LUNG NEOPLASIA, DNA AND RNA ANALYSIS, 23 GENES, INTERROGATION FOR SEQUENCE VARIANTS AND REARRANGEMENTS, REPORTED AS PRESENCE/ABSENCE OF VARIANTS AND ASSOCIATED THERAPY(IES) TO CONSIDER

ICD-10 Codes that are Covered

Group 1 Paragraph:

N/A

Group 1 Codes:

ICD-10 CODE	DESCRIPTION
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
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
C34.30	Malignant neoplasm of lower lobe, unspecified 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
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and 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
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or 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 Codes that are Not Covered

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
07/05/2018	R3	Revised article to add the PLA code 0022U, effective 10/1/2017.
02/26/2018	R2	The Jurisdiction "J" Part A and Part B Contracts for Alabama (10111/10112), Georgia (10211/10212) and Tennessee (10311/10312) are now being serviced by Palmetto GBA. Effective 02/26/18, these 6 contract numbers are being added to this article. No coverage, coding or other substantive changes (beyond the addition of the 6 Part A and B contract numbers) have been completed in this revision.
02/01/2018	R1	Revised the article to add ICD-10 codes: C33, C34.00, C34.01, C34.02, C34.10, C34.11, C34.12, C34.2, C34.30, C34.31, C34.32, C34.80, C34.81, C34.82, C34.90, C34.91, C34.92.

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 06/29/2018 with effective dates 07/05/2018 - N/A
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

Keywords

N/A