Local Coverage Article:
MolDX: FDA Approved CLL Companion Diagnostic Test Coding and Billing Guidelines (A56008)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

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
A56008

Article Title
MolDX: FDA Approved CLL Companion Diagnostic Test Coding and Billing Guidelines

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

Original Effective Date
06/07/2018

Revision Effective Date
N/A

Revision Ending Date
N/A

Retirement Date
N/A

Article Guidance

Article Text:

Effective April 11, 2016, the FDA approved venetoclax (VENCLEXTA®/AbbVie), a new drug treatment for patients with B-cell chronic lymphocytic leukemia (CLL) with 17p deletion and at least one prior therapy, and a new indication for Vysis CLL FISH Probe Kit, a laboratory test to detect 17p deletion, as a companion diagnostic for venetoclax.

Venetoclax is an inhibitor that binds directly to the BCL-2 protein whose overexpression has been associated with resistance to chemotherapeutics. The 17p deletion is more frequently observed in treated patients than in patients who have received no treatment. Therefore, venetoclax has been approved for patients with previous treatment for CLL with the 17p deletion as detected by the Vysis CLL FISH Probe Kit. Vysis CLL FISH Probe Kit is not intended for monitoring of residual disease.

Palmetto GBA will only cover 17p deletion detection by FISH testing services when performed using validated assays. To date, Vysis CLL FISH Probe Kit is the only FDA validated and approved assay for the detection of the 17p deletion as the companion diagnostic for Venetoclax. Vysis CLL FISH Probe Kit services may only be billed by a CLIA certified lab. Vysis Fish Probe Kit by Abbott Molecular meets the reasonable and necessary criteria for Medicare reimbursement.

To report a Vysis FISH Probe kit service, please submit the following claim information:

1. When medically necessary and enumeration is performed, reviewed, and interpreted by a physician or pathologist:
    - Select the CPT code 88374 or 88377 for your service as appropriate and enter 2 units of service (UOS)
2. When medically necessary and enumeration is performed and reviewed by a cytotechnologist
    - Select the CPT code 88271 and 88275 for your service as appropriate and enter 4 units and 1 unit of service respectively (UOS)
    - Select the CPT code 88291 with 1 unit of service for physician interpretation

Additional Information: To bill the PC component, the pathologist must read and interpret the raw data. Per Chapter 10, Version 16.3 in the NCCI Policy Manual for Medicare Services, physicians may not report the professional component provided by the technician or scientist.

Note: This MolDX coding and billing guideline ONLY applies to the UNMODIFIED, Vysis CLL FISH Probe Kit by Abbott for patients with CLL who have received at least one prior therapy and who are potential candidates for venetoclax.

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
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse

ICD-10 Codes that are Not Covered

N/A

Revision History Information

N/A

Associated Documents

Related Local Coverage Document(s)

N/A

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 05/31/2018 with effective dates 06/07/2018 - N/A

Keywords

N/A