

# Local Coverage Article: Billing and Coding: MoIDX: FDA Approved CLL Companion Diagnostic Test (A56009)

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## Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01911 - MAC A	J - E	American Samoa California - Entire State Guam Hawaii Nevada Northern Mariana Islands

## Article Information

### General Information

**Article ID**

A56009

**Original Effective Date**

06/15/2018

**Article Title**

Billing and Coding: MoIDX: FDA Approved CLL  
Companion Diagnostic Test

**Revision Effective Date**

12/01/2019

**Article Type**

Billing and Coding

**Revision Ending Date**

N/A

**AMA CPT / ADA CDT / AHA NUBC Copyright Statement**

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**Retirement Date**

N/A

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**CMS National Coverage Policy**

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.

MolDX 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 billing and coding 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.

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## Coding Information

### CPT/HCPCS Codes

### Group 1 Paragraph:

N/A

### Group 1 Codes:

CODE	DESCRIPTION
88271	MOLECULAR CYTOGENETICS; DNA PROBE, EACH (EG, FISH)
88275	MOLECULAR CYTOGENETICS; INTERPHASE IN SITU HYBRIDIZATION, ANALYZE 100-300 CELLS
88291	CYTOGENETICS AND MOLECULAR CYTOGENETICS, INTERPRETATION AND REPORT
88374	MORPHOMETRIC ANALYSIS, IN SITU HYBRIDIZATION (QUANTITATIVE OR SEMI-QUANTITATIVE), USING COMPUTER-ASSISTED TECHNOLOGY, PER SPECIMEN; EACH MULTIPLEX PROBE STAIN PROCEDURE
88377	MORPHOMETRIC ANALYSIS, IN SITU HYBRIDIZATION (QUANTITATIVE OR SEMI-QUANTITATIVE), MANUAL, PER SPECIMEN; EACH MULTIPLEX PROBE STAIN PROCEDURE

### CPT/HCPCS Modifiers

N/A

### ICD-10 Codes that Support Medical Necessity

#### 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 DO NOT Support Medical Necessity

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 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

**Other Coding Information**

N/A

## Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
12/01/2019	R1	As required by CR 10901, article is converted to a formal billing and coding type article. There is no change in coverage.  Added CPT codes 88271, 88275, 88291, 88374, 88377 to the CPT/HCPCS section

## 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 12/11/2019 with effective dates 12/01/2019 - N/A

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# Keywords

- 88271
- 88275
- 88291
- 88374
- 88377
- MoIDX
- Vysis
- FISH
- venetoclax
- VENCLEXTA®/AbbVie
- CLL
- leukemia