## Contractor Information

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

## Article Information

### General Information

Created on 12/19/2019. Page 1 of 6
Article ID
A56009

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

Article Type
Billing and Coding

AMA CPT / ADA CDT / AHA NUBC Copyright
Statement
CPT codes, descriptions and other data only are
Copyright © 2018 American Medical Association. All Rights
Reserved. Applicable FARS/HHSARS apply.

Current Dental Terminology © 2018 American Dental
Association. All rights reserved.

Copyright © 2019, the American Hospital Association,
Chicago, Illinois. Reproduced with permission. No
portion of the AHA copyrighted materials contained
within this publication may be copied without the
express written consent of the AHA. AHA copyrighted
materials including the UB-04 codes and descriptions
may not be removed, copied, or utilized within any
software, product, service, solution or derivative work
without the written consent of the AHA. If an entity
wishes to utilize any AHA materials, please contact the
AHA at 312-893-6816. Making copies or utilizing the
content of the UB-04 Manual, including the codes and/or
descriptions, for internal purposes, resale and/or to be
used in any product or publication; creating any
modified or derivative work of the UB-04 Manual and/or
codes and descriptions; and/or making any commercial
use of UB-04 Manual or any portion thereof, including
the codes and/or descriptions, is only authorized with an
express license from the American Hospital Association.
To license the electronic data file of UB-04 Data
Specifications, contact Tim Carlson at (312) 893-6816
or Laryssa Marshall at (312) 893-6814. You may also
contact us at ub04@healthforum.com.

CMS National Coverage Policy
N/A

Article Guidance
Created on 12/19/2019. Page 2 of 6
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.

## Coding Information

### CPT/HCPCS Codes

**Group 1 Paragraph:**
N/A

**Group 1 Codes:**
<table>
<thead>
<tr>
<th>CODE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>88271</td>
<td>MOLECULAR CYTOGENETICS; DNA PROBE, EACH (EG, FISH)</td>
</tr>
<tr>
<td>88275</td>
<td>MOLECULAR CYTOGENETICS; INTERPHASE IN SITU HYBRIDIZATION, ANALYZE 100-300 CELLS</td>
</tr>
<tr>
<td>88291</td>
<td>CYTOGENETICS AND MOLECULAR CYTOGENETICS, INTERPRETATION AND REPORT</td>
</tr>
<tr>
<td>88374</td>
<td>MORPHOMETRIC ANALYSIS, IN SITU HYBRIDIZATION (QUANTITATIVE OR SEMI-QUANTITATIVE), USING COMPUTER-ASSISTED TECHNOLOGY, PER SPECIMEN; EACH MULTIPLEX PROBE STAIN PROCEDURE</td>
</tr>
<tr>
<td>88377</td>
<td>MORPHOMETRIC ANALYSIS, IN SITU HYBRIDIZATION (QUANTITATIVE OR SEMI-QUANTITATIVE), MANUAL, PER SPECIMEN; EACH MULTIPLEX PROBE STAIN PROCEDURE</td>
</tr>
</tbody>
</table>

CPT/HCPCS Modifiers
N/A

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph:
N/A

Group 1 Codes:

<table>
<thead>
<tr>
<th>ICD-10 CODE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>C91.10</td>
<td>Chronic lymphocytic leukemia of B-cell type not having achieved remission</td>
</tr>
<tr>
<td>C91.12</td>
<td>Chronic lymphocytic leukemia of B-cell type in relapse</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>REVISION HISTORY DATE</th>
<th>REVISION HISTORY NUMBER</th>
<th>REVISION HISTORY EXPLANATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/01/2019</td>
<td>R1</td>
<td>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</td>
</tr>
</tbody>
</table>

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

Created on 12/19/2019. Page 5 of 6
Keywords

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