

# Local Coverage Article: MolDX: Clonoseq® Assay for Assessment of Minimal Residual Disease (MRD) in Patients with Specific Lymphoid Malignancies (A56322)

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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**

A56322

**Original Article Effective Date**

03/04/2019

**Article Title**

MoIDX: Clonoseq® Assay for Assessment of Minimal Residual Disease (MRD) in Patients with Specific Lymphoid Malignancies

**Revision Effective Date**

N/A

**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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## Article Guidance

## Article Text:

[clonoSEQ® Technical Information](#) Medicare published a National Coverage Decision, 90.2 Next-Generation Sequencing for Patients with Advanced Cancer with an effective date of 03/16/2018. This coverage decision allows Medicare Administrative Contractors to cover a next generation sequencing test for cancer diagnoses in beneficiaries with advanced cancer who are seeking additional treatment. Contractors may cover up to one test per beneficiary per cancer diagnosis.

Minimal Residual Disease (MRD) refers to a measure of cancer cells that remain in a person during and following treatment. Clinical practice guidelines in a number of hematological malignancies recommend MRD testing and recognize MRD status as a reliable indicator of clinical outcome and response to therapy, which is currently recommended in the course of treatment of patients with acute lymphoblastic leukemia (ALL) or multiple myeloma (MM). (1,2)

The clonoSEQ Assay was granted *de novo* designation by the FDA and is the only MRD assessment tool to have received FDA clearance for the measurement of MRD in patients with B-Cell ALL or MM. (3) The test is indicated for use by qualified healthcare professionals in accordance with professional guidelines for clinical decision-making and in conjunction with other clinicopathological features. The clonoSEQ Assay is a single-site assay performed at Adaptive Biotechnologies Corporation using multiplex polymerase chain reaction and next generation sequencing of DNA, which is able to detect lower quantities of MRD than flow cytometry (4).

Testing for MRD using the clonoSEQ Assay is constituted by a series of assays in time, starting with a baseline assay that identifies clonal sequences, which will be tracked. Measurements of residual disease based on quantification of clonal sequences identified during the baseline are then reassessed in subsequent assays, allowing a provider to monitor response to therapy. Information obtained from this testing is recommended to be used to decide on whether and when to pursue additional treatment.

Effective 03/16/2018, molDX has determined that clonoSEQ Assay testing is reasonable and necessary when performed on bone marrow specimens in patients with B-Cell acute lymphoblastic leukemia (ALL) or multiple myeloma. Medicare will pay for a single episode of testing using clonoSEQ in these patients. For a patient with ALL or multiple myeloma in whom clonoSEQ is being used according to its FDA cleared indications and clinical guidelines, it is anticipated that an episode of testing will typically require a baseline assay and 3 follow-up assays. This service should be billed at the start of the episode of testing.

Coverage of clonoSEQ for other lymphoid cancer indications and episodes of care, and modifications to the definition of an episode of care will be evaluated on an annual basis.

To report a **clonoSEQ** episode of testing service, please submit the following claim information:

- Select the CPT 81479 for claims on or after 3/16/2018.
- 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 form

The following diagnoses are appropriate for the test. Select the appropriate ICD-10-CM code:

#### Multiple Myeloma

- C90.00 Multiple myeloma not having achieved remission
- C90.01 Multiple myeloma in remission
- C90.02 Multiple myeloma in relapse

#### Acute Lymphoblastic Leukemia (ALL)

- C91.00 Acute lymphoblastic leukemia not having achieved remission
- C91.01 Acute lymphoblastic leukemia, in remission
- C91.02 Acute lymphoblastic leukemia, in relapse

#### **References:**

1. National Comprehensive Cancer Network (NCCN). [NCCN Clinical Practice Guidelines in Oncology \(NCCN Guidelines®\). Acute Lymphoblastic Leukemia \(Version 1.2019\)](#). Accessed 12/16/2018
2. National Comprehensive Cancer Network (NCCN). [NCCN Clinical Practice Guidelines in Oncology \(NCCN Guidelines®\). Multiple Myeloma \(Version 2.2019\)](#). Accessed 12/16/2018
3. Food and Drug Administration. [FDA authorizes first next generation sequencing-based test to detect very low levels of remaining cancer cells in patients with acute lymphoblastic leukemia or multiple myeloma](#). Accessed 12/17/18
4. Adaptive Biotechnologies. [clonoSEQ® Technical Information](#). Accessed 12/17/2018

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## 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
81479	UNLISTED MOLECULAR PATHOLOGY PROCEDURE

**ICD-10 Codes that are Covered****Group 1 Paragraph:**

N/A

**Group 1 Codes:**

ICD-10 CODE	DESCRIPTION
C90.00	Multiple myeloma not having achieved remission
C90.01	Multiple myeloma in remission
C90.02	Multiple myeloma in relapse
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.01	Acute lymphoblastic leukemia, in remission
C91.02	Acute lymphoblastic leukemia, in relapse

**ICD-10 Codes that are Not Covered**

N/A

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## Revision History Information

N/A

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## 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 02/21/2019 with effective dates 03/04/2019 - N/A

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## Keywords

- 81479
- MoIDX
- clonoSEQ®
- Assay
- Assessment
- Minimal Residual Disease
- Lymphoid