Local Coverage Article:
Billing and Coding: MolDX: ClonoSEQ® Assay for Assessment of Minimal Residual Disease (MRD) in Patients with Specific Lymphoid Malignancies (A56270)

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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
A56270

Article Title
Billing and Coding: MolDX: ClonoSEQ® Assay for Assessment of Minimal Residual Disease (MRD) in Patients with Specific Lymphoid Malignancies

Article Type
Billing and Coding

Original Effective Date
01/17/2019

Revision Effective Date
01/01/2020

Revision Ending Date
N/A

Retirement Date
N/A

CMS National Coverage Policy

CMS Internet-Only Manual, Pub. 100-03, National Coverage Determination, §90.2

CMS Internet-Only Manual, Pub. 100-03, Medicare National Coverage Determinations, CR 10878 Program Memorandum Transmittal 215 4/10/2019

Article Guidance

Article Text:

clonoSEQ® Technical InformationMedicare 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 burden that remains 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)$_2$ or multiple myeloma (MM), and chronic lymphocytic leukemia (CLL). (1,2,3)

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 ClonoSEQ Assay has received State of New York Clinical Laboratory Evaluation Program (CLEP) approval for B-cell malignancies. 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 (4,5).

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

Chronic Lymphocytic Leukemia (CLL)

- C91.10 Chronic lymphocytic leukemia not having achieved remission
- C91.11 Chronic lymphocytic leukemia, in remission
- C91.12 Chronic lymphocytic 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. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Chronic Lymphocytic Leukemia / Small Lymphocytic Lymphoma (Version 2.2020). https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed 11/13/2019
5. Adaptive Biotechnologies. clonoSEQ® Technical Information. Accessed 12/17/2018

Coding Information

CPT/HCPCS Codes

Group 1 Paragraph:

N/A

Group 1 Codes:

CODE	DESCRIPTION
81479	UNLISTED MOLECULAR PATHOLOGY 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
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
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.11	Chronic lymphocytic leukemia of B-cell type in 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
01/01/2020	R4	Under **Article Text** in the second paragraph the word cells was changed to burden and a "s" was added to the word remain. Subscript 2 was added after the acronym (ALL) . The subscripts at the end of the paragraph were changed to (1,2,3).The word "or" was removed and "and chronic lymphocytic leukemia(CLL) was added. In the third paragraph added the sentence "The ClonoSEQ® Assay has received State of New York Clinical Laboratory Evaluation Program (CLEP) approval for B-cell malignancies." And changed the subscripts to (4,5). Also added Chronic Lymphocytic Leukemia (CLL) • C91.10 Chronic lymphocytic leukemia not having achieved remission • C91.11 Chronic lymphocytic leukemia, in remission • C91.12 Chronic lymphocytic leukemia, in relapse. Under **ICD-10 Codes that Support Medical Necessity Group 1:** *Codes* added C91.10, C91.11 and C91.12. This revision is due to the Annual ICD-10 Code Update and becomes effective on 1/1/20.
11/21/2019	R3	This article is being revised in order to adhere to CMS requirements per Chapter 13, section 13.5.1 of the Program Integrity Manual, to remove all coding from LCDs and incorporate into related Billing and Coding Articles. Under **Article Title** changed title from Billing and Coding: MolDX: Clonoseq® Assay for Assessment of Minimal Residual Disease (MRD) in Patients with Specific Lymphoid Malignancies to Billing and Coding: MolDX: ClonoSEQ® Assay for Assessment of Minimal Residual Disease (MRD) in Patients with Specific Lymphoid Malignancies. Under **CMS National Coverage Policy** section added CMS Internet-Only Manual, Pub. 100-03, National Coverage Determination, §90.2 and CMS Internet-Only Manual, Pub. 100-03, Medicare National Coverage Determinations, CR 10878, Program Memorandum Transmittal 215 4/10/2019. Registered symbols were added to the trade name ClonoSEQ®, CPT® was inserted and typographical errors were corrected throughout the article.

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
01/31/2019	R2	Corrected link in reference #4.
01/24/2019	R1	Corrected year in first paragraph from 208 to 2018 and correcting the broken link in reference #4.

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 12/12/2019 with effective dates 01/01/2020 - N/A
Updated on 11/11/2019 with effective dates 11/21/2019 - N/A
Updated on 01/24/2019 with effective dates 01/31/2019 - N/A
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

Keywords

- CloneSEQ
- MRD