


MEDICAL POLICY	Next Generation Sequencing for Minimal Residual Disease Detection (Medicare Only)
Effective Date: 6/1/2021  <div style="text-align: right;">6/1/2021</div>	Medical Policy Number: 111
	Medical Policy Committee Approved Date: 3/2020; 5/2021
Medical Officer	Date

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Aycin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

Medicare Only

MEDICARE POLICY CRITERIA	
<p>The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.</p>	
Service	Medicare Guidelines
<i>Next Generation Sequencing for Leukemias or Myelomas (ClonoSeq Assay)</i>	<ul style="list-style-type: none"> National Coverage Determination (NCD) for Next Generation Sequencing (NGS) (90.2)¹ Local Coverage Article: Billing and Coding: MoIDX: ClonoSEQ Assay for Assessment of Minimal Residual Disease in Patients with Specific Lymphoid Malignancies (A56323)²
<i>Minimal Residual Disease Testing for Colorectal Cancer</i>	<ul style="list-style-type: none"> Local Coverage Determination (LCD): MoIDX: Minimal Residual Disease Testing for Colorectal Cancer (L38431)³ Local Coverage Article: Billing and Coding: MoIDX: Minimal Residual Disease Testing for Colorectal Cancer (A57104)⁴

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BILLING GUIDELINES

Clonoseq Assay (Adaptive Biotechnologies) will only pay when billed with any of the following ICD-10 codes:

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

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

CPT/HCPCS CODES

Medicare Only	
<p>Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then prior-authorization is required.</p>	
81479	Unlisted molecular pathology procedure

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

REFERENCES

1. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Next Generation Sequencing (NGS) (90.2). <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=372>. Published 2018. Accessed 3/16/2021.
2. Centers for Medicare & Medicaid Services. Local Coverage Article: Billing and Coding: MoIDX: ClonoSEQ® Assay for Assessment of Minimal Residual Disease (MRD) in Patients with Specific Lymphoid Malignancies (A56323). <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=56323>. Published 2019. Accessed 3/16/2021.
3. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): MoIDX: Minimal Residual Disease Testing for Colorectal Cancer (L38431). <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=38431>. Published 2020. Accessed 4/20/2021.
4. Centers for Medicare & Medicaid Services. Local Coverage Article: Billing and Coding: MoIDX: Minimal Residual Disease Testing for Colorectal Cancer (A57104). <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=57104>. Published 2020. Accessed 4/20/2021.