


<b>MEDICAL POLICY</b>	<b>Minimal Residual Disease Detection in Lymphoid Malignancies (Medicare Only)</b>	
<b>Effective Date: 6/1/2020</b>   <div style="text-align: right;">6/1/2020</div>	Section: LAB	Policy No: 424
	Medical Policy Committee Approved Date: 3/2020;	
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 Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

**APPLIES TO:**

Medicare Only

**MEDICARE POLICY CRITERIA**

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.

Service	Medicare Guidelines
<i>Next Generation Sequencing for Leukemias or Myelomas (ClonoSeq Assay)</i>	<ul style="list-style-type: none"> <li>National Coverage Determination (NCD) for Next Generation Sequencing (NGS) (<a href="#">90.2</a>)<sup>1</sup></li> <li>Local Coverage Article: Billing and Coding: MoIDX: ClonoSEQ Assay for Assessment of Minimal Residual Disease in Patients with Specific Lymphoid Malignancies (<a href="#">A56323</a>)<sup>2</sup></li> </ul>

**BILLING GUIDELINES**

Clonoseq 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

<b>MEDICAL POLICY</b>	<b>Minimal Residual Disease Detection in Lymphoid Malignancies (Medicare Only)</b>
-----------------------	----------------------------------------------------------------------------------------

- 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**

<b>Medicare Only</b>	
<p>Unlisted Codes</p> <p>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 <b>prior-authorization is required.</b></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.

**REFERENCES**

- 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 1/16/2020.

<b>MEDICAL POLICY</b>	<b>Minimal Residual Disease Detection in Lymphoid Malignancies (Medicare Only)</b>
-----------------------	----------------------------------------------------------------------------------------

- 2. Centers for Medicare & Medicaid Services. Local Coverage Article: Billing and Coding: MolDX: 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 1/16/2020.