MEDICAL POLICY

Minimal Residual Disease Detection in Lymphoid Malignancies (Medicare Only)

Effective Date: 6/1/2020

Section: LAB  
Policy No: 424

Medical Policy Committee Approved Date: 3/2020;

6/1/2020

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.

<table>
<thead>
<tr>
<th>Service</th>
<th>Medicare Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Next Generation Sequencing for Leukemias or Myelomas (ClonoSeq Assay)</td>
<td>- National Coverage Determination (NCD) for Next Generation Sequencing (NGS) (90.2)¹</td>
</tr>
<tr>
<td></td>
<td>- Local Coverage Article: Billing and Coding: MoIDX: ClonoSEQ Assay for Assessment of Minimal Residual Disease in Patients with Specific Lymphoid Malignancies (A56323)²</td>
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</tbody>
</table>

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
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- 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

<table>
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<th>Medicare Only</th>
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<tbody>
<tr>
<td>Unlisted Codes</td>
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</table>

| 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