MEDICAL POLICY	Next Generation Sequencing for Minimal Residual Disease Detection (Medicare Only)
Effective Date: 7/1/2022  7/1/2022 Medical Officer Date	Medical Policy Number: 111 Medical Policy Committee Approved Date: 3/2020; 5/2021; 2/2022; 3/2022; 6/2022

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.

Note: This policy only addresses the use of next generation sequencing (NGS) for minimal residual disease (MRD) detection. Other MRD techniques (e.g., flow cytometry, polymerase chain reaction [PCR]) are not addressed in this Company medical policy, but may be included within the Medicare citations below.

Service	Medicare Guidelines

Next Generation Sequencing (NGS) Minimal Residual Disease (MRD) Testing - General Criteria
 	
(e.g., ClonoSeq, Signatera, Guardant Reveal)
	General coverage criteria (for all indications):
	
	• Local Coverage Determination (LCD) for MolDX: Minimal Residual Disease Testing for Cancer
	  ○ Testing performed in OR, WA, AK, ID, UT, AZ, MT, ND, SD, WY: L38816
	  ○ Testing performed in CA or NV: L38814
	
	Specific test coverage: LCDs L38816/L38814 require successful completion of a technical assessment (TA) by the Medicare Molecular

	Diagnostics (MolDX) contractor. **Not all commercially available tests may be medically necessary** (each LCA below includes covered tests for that indication).
Important Note for All of the Following LCAs: • Clinical criteria: The member must meet the *clinical* criteria from either LCD L38816 or L38814 (e.g., personal history of cancer, advanced stage, no prior testing, expects further treatments, etc.). • Test criteria: The following LCAs list covered tests which **have** met the LCD *test* requirements. See "Policy Guidelines" for additional coverage information for select tests. **If a test is not listed as "covered" for MRD testing, the above LCD *test* requirement criteria are not met.**	
NGS MRD Tests for Leukemias or Lymphoid Malignancies	For the **ClonoSEQ®** Assay for **lymphoid malignancies**: • LCA for Billing and Coding: MolDX: ClonoSEQ Assay for Assessment of Minimal Residual Disease in Patients with Specific Lymphoid Malignancies (A56323) *(MolDX expanded coverage for this test beyond what is published in this LCA. Therefore, LCAs below should also be considered.)* For **additional coverage for ClonoSEQ®, as well as other MRD tests for hematologic cancers**: • LCA for Billing and Coding: MolDX: Minimal Residual Disease Testing for **Hematologic Cancers**: ○ Testing performed in OR, WA, AK, ID, UT, AZ, MT, ND, SD, WY: A58997 ○ Testing performed in CA or NV: A58996
NGS MRD Tests for Colorectal Cancer	• LCAs for Billing and Coding: MolDX: Minimal Residual Disease Testing for **Colorectal Cancer:** ○ Testing performed in OR, WA, AK, ID, UT, AZ, MT, ND, SD, WY: A58449 ○ Testing performed in CA or NV: LCA for Billing and Coding: A58448
NGS MRD Tests for Other Solid Tumor Cancers	• LCAs for Billing and Coding: MolDX: Minimal Residual Disease Testing for **Solid Tumor Cancers**: ○ Testing performed in OR, WA, AK, ID, UT, AZ, MT, ND, SD, WY: A58456 ○ Testing performed in CA or NV: A58454

POLICY GUIDELINES

Related panel tests include:

Note: This list was accurate at the time of publication, but it is subject to change at any time by the Medicare MolDX Program contractor.

Proprietary Test Name	Laboratory	MolDX TA Review Outcome (as found in the DEX™ Diagnostics Exchange registry)
Invitae PCM Tissue Profiling and MRD Baseline Assay (0306U)	Invitae Corporation (California)	Not Covered
Invitae PCM MRD Monitoring (0307U)	Invitae Corporation (California)	Not Covered
ClonoSeq	Adaptive Biotechnologies (Washington)	Covered
Signatera	Natera Inc. (California)	Covered
Guardant Reveal	Guardant Health (California)	Not Covered

CPT/HCPCS CODES

Medicare Only	
Not Covered	
0306U	Oncology (minimal residual disease [MRD]), next-generation targeted sequencing analysis, cell-free DNA, initial (baseline) assessment to determine a patient-specific panel for future comparisons to evaluate for MRD
0307U	Oncology (minimal residual disease [MRD]), next-generation targeted sequencing analysis of a patient-specific panel, cell-free DNA, subsequent assessment with comparison to previously analyzed patient specimens to evaluate for MRD
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.**	
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.