Subject: Genetic Testing for Circulating Tumor DNA Tests for Management of Cancer

Medical Policy #: 54.0 **Original Effective Date:** 03-22-2023

Status: New **Last Review Date: N/A**

Disclaimer

Refer to the member's specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans or the plan may have broader or more limited benefits than those listed in this Medical Policy.

Description

Minimal Residual Disease (MRD) testing for cancer is rapidly becoming a sensitive and specific method for monitoring the relative amounts of tumor-derived genetic material circulating in the blood of cancer patients. These tests leverage new genomic technologies that allow detection of extremely dilute tumor material, yielding an extremely sensitive method for determining the continued presence of tumor material or, buy serially testing the same individual, tracking the relative increase or decrease of tumor material being deposited in the blood. Although it is a relatively new application of novel genomic technologies, it has rapidly demonstrated its ability to impact patient care in several ways in cancer diagnosis and treatment. MRD testing can be used to:

- diagnose cancer progression, recurrence, or relapse before there is clinical, biological, or radiographical evidence of progression, recurrence, or relapse
- detect tumor response to therapy by measuring the proportional changes in the amount of available tumor DNA

Both above uses may enable physicians to better assign risk stratification, deploy alternate treatment strategies, or preclude the use of unnecessary adjuvant therapies.

Coverage Determination

Prior Authorization is required. Logon to Pres Online to submit a request: https://ds.phs.org/preslogin/index.jsp

Presbyterian follows CMS, LCD MolDX: Minimal Residual Disease Testing for Cancer (L38835) for MRD in solid tumor (Signatera), and MRD in Hematopoietic (ClonoSeq®) for Medicare, Medicaid and Commercial. The related articles are:

- For Signatera™ see LCA (A58468), MolDX: Minimal Residual Disease Testing for Solid Tumor Cancers.
- For ClonoSEQ ® see LCA (A59004), MolDX Minimal Residual Disease Testing for Hematologic Cancers

Coding

The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.

CPT Codes	Description	For covered diagnoses see:
0340U	Oncology (pan-cancer), analysis of minimal residual disease (MRD) from plasma, with assays personalized to each patient based on prior next-generation sequencing of the patient's tumor and germline DNA, reported as absence or presence of MRD, with disease-burden correlation, if appropriate. Includes Signatera™, Natera, Inc	A58468 - Billing and Coding: MolDX: Minimal Residual Disease Testing for Solid Tumor Cancers,
81479	Unlisted molecular pathology procedure For ClonoSeq.	A59004 - Billing and Coding: MolDX: Minimal Residual Disease Testing for Hematologic Cancers

Reviewed by / Approval Signatures

Clinical Quality & Utilization Mgmt. Committee: Gray Clarke MD
Senior Medical Director: David Yu MD
Medical Director: Ana Maria Rael MD
Date Approved: March 22, 2023

References

1. CMS, LCD MolDX: Minimal Residual Disease Testing for Cancer (L38835), revision date 12/26/2021, R1; [Cited 01/31/2023]
   Related Articles:
   a. A59004 - Billing and Coding: MolDX: Minimal Residual Disease Testing for Hematologic Cancers, revision date: 01/01/2023, R3
   b. A58468 - Billing and Coding: MolDX: Minimal Residual Disease Testing for Solid Tumor Cancers, revision date: 01/01/2023, R4
2. CMS, LCD Biomarkers Overview (L35062) Revision 22, related article (A56541), revision date 08-03-022, R5 [Cited 01/31/2023]
3. Hayes, Signatera (Natera Inc.), Molecular Test assessment, Jan 18, 2023 [Cited 01/31/2023]
4. Hayes, Signatera (Natera Inc.), Precision Medicine Research Brief, May 04, 2021 [Cited 01/31/2023
5. Hayes, clonoSEQ (Adaptive Biotechnologies), Molecular Test Assessment, Jun 22, 2022 [Cited 01/31/2023]
6. AMA, CPT® Proprietary Laboratory Analyses (PLA) Codes: Long Descriptors, Updated December 29, 2022 [Cited 02/01/2023]

Publication History

03-22-2023 Original effective date. New policy. Reviewed by PHP Medical Policy Committee on 02-01-2023. Coverage will follow WPS, MolDX: Minimal Residual Disease Testing for Cancer LCD (L38835) for molecular residual disease assay (MRD) using ctDNA for management of Cancer for ALOB. Test includes:

- Signatera™ by Natera. Code 0340U effective 10/01/2022. Related article LCA (A58468). Code will require PA.
- ClonoSEQ® by Adaptive Biotechnologies. Code 81479. Related article LCA (A59004). Code will require PA. *AMA future PLA Code (0364U) to be published in 2024.

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such. For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: ***Click here for Medical Policies***

Web links:
At any time during your visit to this policy and find the source material web links has been updated, retired or superseded, PHP is not responsible for the continued viability of websites listed in this policy.

When PHP follows a particular guideline such as LCDs, NCDs, MCG, NCCN etc., for the purposes of determining coverage; it is expected providers maintain or have access to appropriate documentation when requested to support coverage. See the References section to view the source materials used to develop this resource document.