

Subject: Genetic Testing, Plasma-Based Genomic Profiling in Solid Tumors

Medical Policy #: 39.0

Original Effective Date: 05-20-2020

Status: Reviewed

Last Review Date: 03-20-2024

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.

Coverage Determination

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

Covered services to members of **Commercial, Medicaid and Medicare** based on the following.

Presbyterian Health Plan follows Local Coverage Determination ([L38168](#)), MoIDX: Plasma-Based Genomic Profiling in Solid Tumors and the related LCA ([A57936](#))

See also Genetic Testing, InvisionFirst Liquid Biopsy, (by Inivata) for Lung Cancer, MPM 39.1

Coding

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

CPT/HCPCS Codes	Description
81445	Solid organ neoplasm, genomic sequence analysis panel, 5-50 genes, interrogation for sequence variants and copy number variants or rearrangements, if performed; DNA analysis or combined DNA and RNA analysis
81479	Unlisted molecular pathology procedure
0326U	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 83 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden. Guardant360®, Guardant Health, Inc, Guardant Health, Inc
0409U	Oncology (solid tumor), DNA (80 genes) and RNA (36 genes), by next-generation sequencing from plasma, including single nucleotide variants, insertions/deletions, copy number alterations, microsatellite instability, and fusions, report showing identified mutations with clinical actionability
0428U	Oncology (breast), targeted hybrid-capture genomic sequence analysis panel, circulating tumor DNA (ctDNA) analysis of 56 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability, and tumor mutation burden

CPT/HCPCS Codes	Non-Covered
0179U	Oncology (non-small cell lung cancer), cell-free DNA, targeted sequence analysis of 23 genes (single nucleotide variations, insertions and deletions, fusions without prior knowledge of partner/breakpoint, copy number variations), with report of significant mutation(s)

ICD-10 Codes
See MoIDX: Plasma-Based Genomic Profiling in Solid Tumors (A57936) for covered diagnoses.

Population Health and Clinical Quality Committee (PHCQC): Gray Clarke MD

Medical Director: Ana Maria Rael MD

Date Approved: 03-20-2024

References

1. CMS, Wisconsin Physician Service Ins. Corp, Local Coverage Determination (LCD) L38168, MoIDX: Plasma-Based Genomic Profiling in Solid Tumors, Original Effective Date: 03-15-2020, Revision date: 10/26/2023, R3 [Cited 02/20/2024]
2. CMS related Local Coverage Article, Billing and Coding: MoIDX: Plasma-Based Genomic Profiling in Solid Tumors (A57936), Revision History date: 10/01/2023, R9. [Cited 02/20/2024]
3. CMS, WPS, LCD (L38835) MoIDX: Minimal Residual Disease Testing for Cancer, Revision History Date, 10/26/2023, R2 [Cited 02/20/2024]
 - a. LCA (A58468), Billing and Coding MoIDX: Minimal Residual Disease Testing for Solid Tumor Cancers, Revision date: 01/01/2024, R6
 - b. LCA (A59004), Billing and Coding: MoIDX: Minimal Residual Disease Testing for Hematologic Cancers, Revision date: 01/01/2024, R4
4. Hayes A TractManager Company, Guardant360 (Guardant Health Inc.), Molecular Test Assessment, 12/11/2018, Annual Review May 23, 2023 . [Cited 02/10/2023]
5. Hayes A TractManager Company, FoundationOne Liquid (Foundation Medicine Inc), (insufficient evidence), Jun 13, 2019, Annual Review Apr 26, 2022. [Cited 02/22/2024]
6. Hayes, Resolution ctDx Lung (Resolution Bioscience Inc.), Precision Medicine Research Brief, Nov 20, 2020, SOMATIC, ARCHIVED Dec 20, 2022 [Cited 02/22/2024]

Publication History

- 05-20-2020 New Policy - Technology Assessment Committee evaluation on 04-22-2020: Agreed to Plasma-Based Genomic Profiling in Solid Tumor, (Guardant360) test and to follow MoIDX LCD L38168 criteria. Recommend coverage of Plasma-based biopsy to all product lines with prior authorization requirement for CPT 81479. Reviewed by PHP Medical Policy Committee on 04-29-20 and agreed with TAC recommendations and place PA requirement for this policy for CPT 81479.
- 03-24-2021 Reviewed on 03/16/2021. Both LCD MoIDX: Plasma-Based Genomic Profiling in Solid Tumors (L38043/A57866), (not NM jurisdiction), (Guardant360), and LCD MoIDX: Plasma-Based Genomic Profiling in Solid Tumors (L38168/LCA-A57936) were reviewed. Hayes says there is insufficient evidence to perform a full assessment of the Resolution ctDx Lung (Resolution Bioscience Inc.) lung test. Did not include CPT 0179U in this review. Update policy with CPT code 81445. Code 81445 and 81479 will continue PA.
- 03-23-2022 Annual review. Reviewed by PHP Medical Policy Committee on 03-04-2022. Continue to cover Guardant360 only and follow LCD L38168 and LCA A57936 for all LOB. Continue PA requirement for 81445 and 81479. Configure 0179U is non-covered per LCA A57936 (group 2), for all LOB.
- 03-22-2023 Annual review. Reviewed by PHP Medical Policy Committee on 02-10-2023. No change. Continue to follow LCD L38168 and LCA A57936 for all LOB, but the coverage determination guideline language has been removed from policy and reformatted to only include LCD/LCA weblinks. Continue PA requirement for 81445 and 81479. Continue non-coverage for 0179U per LCA A57936 (group 2), for all LOB. Add the newly released Jan 2023, code 0326U which will require PA.
- 03-20-2024 Annual review. Reviewed by PHP Medical Policy Committee on 02-23-2024. There is no change in coverage. Continue to follow LCD L38168 and LCA A57936 for ALOB. Continue PA requirement for: 81445, 0326U, 0409U and 81479. Add codes 0409U and 0428U. Correction: LCA (A57867) was erroneously used instead of LCA (A57936) in the coverage section.

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.