Subject: Genetic Testing, InvisionFirst Liquid Biopsy for Lung Cancer

Medical Policy #: 39.1

Status: Reviewed

Original Effective Date: 05-20-2020

Last Annual Review Date: 05-28-2025

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 for Commercial, Medicaid and Medicare.

See also Genetic Testing, Plasma-Based Genomic Profiling in Solid Tumors, MPM 39.0.

Presbyterian Health Plan follows LCD L37921, MolDX: Inivata™ InVisionFirst®, Liquid Biopsy for Patients with Lung Cancer.

Blood-based liquid biopsy InVisionFirst® - Lung test supports the therapeutic decisions at different stages for patients with advanced (Stage IIIB/IV) non-small cell lung cancer (NSCLC) whose tissue is unavailable due to insufficient and/or unobtainable material for tissue-based:

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
81479	InVisionFirst®-Lung, ctDNA Liquid biopsy testing for 36 or 37 genes relevant to advanced NSCLC includes:
0388U	Oncology (non-small cell lung cancer), next-generation sequencing with identification of single nucleotide variants, copy number variants, insertions and deletions, and structural variants in 37 cancer-related genes, plasma, with report for alteration detection

ICD-10	Description
For ICD-10 Codes that support medical necessity please access related policy article Inivata™, InVisionFirst®, Liquid Biopsy for Patients with Lung Cancer (A56333)	

Reviewed by / Approval Signatures

Population Health & Clinical Quality Committee (PHCQ): Clinton White MD
Senior Medical Director: Jim Romero MD
Date Approved: 05/28/2025

References

1. CMS, Wisconsin Physician Service Ins. Corp, Local Coverage Determination (LCD), MolDX: Inivata™, InVisionFirst™, Liquid Biopsy for Patients with Lung Cancer (L37921), Revision Effective Date:11/30/2023, R6 [Cited 05-09-2025]
2. CMS related Local Coverage Article, Billing and Coding MolDX: Inivata™, InVisionFirst®, Liquid Biopsy for Patients with Lung Cancer (A56333). Revision Effective Date 07/01/2023, R4 [Cited 05-09-2025]
3. NCCN, Treatment by Cancer type, Version 3.2025 — January 14, 2025, Non-Small Cell Lung Cancer [Cited 05-09-2025]
4. Hayes, Cell-Free Tumor DNA Testing for EGFR T790M Targeted Mutation in Non-Small Cell Lung Cancer Patients, Feb 09, 2017 (article not found) [Assessed 05-09-2025]
5. Hayes A TractManager Company, Guardant360 (Guardant Health Inc.), Molecular Test Assessment, Aug 01, 2024, [Cited 05-09-2025]
6. Hayes, FoundationOne Liquid CDx (Foundation Medicine Inc.) Nov 22, 2024. [Cited 05-09-2025]
7. Aetna, Tumor Markers, Last Review 04/02/2025, Next review: 04/10/2025 [Cited 05-09-2025]

05-20-2020	New Policy - Technology Assessment Committee evaluation on 04-22-2020: Agreed to create separate policy specific to InvisionFirst for Medicare Only. Policy is to follow LCD L37921 by Wisconsin Physician Service, (in JH). Prior Authorization will be required for CPT 81479.

Reviewed by PHP Medical Policy Committee on 04-29-20 and agreed with TAC recommendations and to place PA requirement for this policy for CPT 81479. |
05-26-2021	Annual review. Reviewed on 05/06/2021. Continue to follow (LCD L37921), MolDX: Inivata, InVisionFirst for Medicare only. Continuation for Commercial/Medicaid as investigational. Removed the exclusions language in regard to "Other noninvasive blood test for non-small cell lung cancer (NSCLC) which are not covered: GeneStrat (Biodesix Inc.) and FoundationOne Liquid (Foundation Medicine Inc)". Continue PA for 81479.
05-25-2022	Annual review. Reviewed by PHP Medical Policy Committee on 04/06/2022. Continue to follow LCD L37921 Inivata™, InVisionFirst®, Liquid Biopsy for Patients with Lung Cancer. Coverage has been expanded to Commercial and Medicaid. Rationale: Both LCD and NCCN mention liquid biopsy testing should only be ordered when tissue-based is infeasible. The coverage determination guideline language removed from policy and reformatted to only include CMS LCD weblinks. The Medical Policy Manual (MPM) number changed from 37.0 to MPM 39.1 to consolidate the Liquid biopsies testing under the MPM 39 category. Throughout the policy added trademark symbol to Inivata and registered symbol to InVisionFirst were added.
05-24-2023	Annual review. Reviewed by PHP Medical Policy Committee on 03-24-2023. Continue to follow LCD L37921 Inivata™, InVisionFirst®, Liquid Biopsy for Patients with Lung Cancer for all LOB.
05-22-2024	Annual review. Reviewed by PHP Medical Policy Committee on May 01, 2024. No change in coverage. Continue to follow WSP LCD (L37921) for ALOB. Add code 0388U, specify to InvisionFirst test for lung cancer. This code already requires PA.
05-28-2025	Annual review. Reviewed by PHP Medical Policy Committee on 05-09-2025. Continue coverage of InVisionFirst®-Lung, ctDNA Liquid biopsy and follow WSP, LCD L37921 for ALOB. Rationale: CMS supports using ctDNA for both diagnosis and progression. Continue PA for 0388U for ALOB. Rationale: Require PA so the test can be reviewed to validate correct usage.

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.