

November
2023



Client Communication

Medicare Local Coverage Determination Policy: CGS

Coverage Policy

L37903- MoIDX: Inivata™, InVisionFirst®, Liquid Biopsy for Patients with Lung Cancer

CPT: 81479

Revision Effective Date: 06/15/2023

Coverage Indications, Limitations, and/or Medical Necessity

This test is a "liquid biopsy". It is intended to assist physicians caring for patients who suffer from a common form of lung cancer and who have advanced disease.

This policy provides limited coverage for InvisionFirst® - Lung (Inivata™, Research Triangle Park, NC) (hereafter InVision®) a plasma-based, somatic comprehensive genomic profiling (CGP) test for patients with advanced (Stage IIIB/IV) non-small cell lung cancer (NSCLC):

- **At diagnosis**

- When results for EGFR single nucleotide variants (SNVs) and insertions and deletions (indels); rearrangements in ALK and ROS1; and SNVs for BRAF are not available **AND** when tissue-based CGP is infeasible [i.e., quantity not sufficient (QNS) for tissue-based CGP or invasive biopsy is medically contraindicated],

or

- **At progression**

- For patients progressing on or after chemotherapy or immunotherapy who have not been tested for EGFR SNVs and indels; rearrangements in ALK and ROS1; and SNVs for BRAFs, and for whom tissue-based CGP is infeasible; **or**
- For patients progressing on EGFR tyrosine kinase inhibitors (TKIs).

Criteria for Coverage

InVision is covered only when the following conditions are met:

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Diagnosis codes must be applicable to the patient's symptoms or conditions and must be consistent with the patient's medical record. Sonic Healthcare does not recommend any diagnosis codes and will only submit diagnosis information provided to us by the ordering physician or his/her designated staff.

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- Patient has been diagnosed with advanced (Stage IIIB or IV) NSCLC; and
- Patient is untreated and results for EGFR-SNV and indels; rearrangement in ALK and ROS1; and SNVs for BRAF, and tissue-based CGP is infeasible [i.e., quantity not sufficient (QNS) for tissue-based CGP or invasive biopsy is medically contraindicated];

or

- Patient is progressing on or after chemotherapy or immunotherapy and has not been tested for EGFR SNVs and indels; rearrangements in ALK, and ROS1; or SNVs for BRAF, and tissue-based CGP is infeasible (i.e. QNS for tissue-based CGP); or
- Patient is progressing on EGFR TKIs

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The ICD10 codes listed below are the top 40 diagnosis codes Sonic most commonly receives from ordering physicians for this limited-coverage test. Medicare supports provider utilization of all the diagnosis codes listed below, except those notated in bold. If you are providing a diagnosis code that is **bolded** below, please submit a valid ABN form with the order. To view the complete policy and the full list of medically supported diagnosis codes, please refer to the CMS website for guidance:

<https://www.cms.gov/medicare-coverage-database/search.aspx>

Code	Description
E03.8	Other specified hypothyroidism
E29.1	Testicular hypofunction
E72.11	Homocystinuria
E78.2	Mixed Hyperlipidemia
R53.83	Other Fatigue
R79.82	Elevated C-reactive protein (CRP)
R94.4	Abnormal results of kidney function studies

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