

Local Coverage Determination (LCD): MolDX: Guardant360® Plasma-Based Comprehensive Genomic Profiling in Non-Small Cell Lung Cancer (NSCLC) (L37651)

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Noridian Healthcare Solutions, LLC	A and B MAC	02101 - MAC A	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02102 - MAC B	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02201 - MAC A	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02202 - MAC B	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02301 - MAC A	J - F	Oregon
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Noridian Healthcare Solutions, LLC	A and B MAC	03101 - MAC A	J - F	Arizona
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Noridian Healthcare Solutions, LLC	A and B MAC	03601 - MAC A	J - F	Wyoming
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[Back to Top](#)

LCD Information

Document Information

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LCD Title
MolDX: Guardant360® Plasma-Based Comprehensive
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Proposed LCD in Comment Period
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CMS National Coverage Policy

Title XVIII of the Social Security Act, §1862(a)(1)(A). Allows coverage and payment for only those services that are considered to be reasonable and necessary.

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42 Code of Federal Regulations (CFR) 410.32(a). Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

CMS On-Line Manual, Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, §§80.0, 80.1.1, 80.2. Clinical Laboratory services.

CMS Internet-Only Manuals, Publication 100-04, Medicare Claims Processing Manual, Chapter 16, §50.5 Jurisdiction of Laboratory Claims, 60.12 Independent Laboratory Specimen Drawing, 60.2. Travel Allowance.

CMS Internet Online Manual Pub. 100-04 (Medicare Claims Processing Manual), Chapter 23 (Section 10) "Reporting ICD Diagnosis and Procedure Codes".

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

This policy provides limited coverage for Guardant360® (Guardant Health, Redwood City, CA), a plasma-based comprehensive somatic genomic profiling test (hereafter called CGP) for patients with Stage IIIB/IV non-small cell lung cancer (NSCLC):

- **At diagnosis** – Untreated Patient

- 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 for tissue-based CGP or invasive biopsy is medically contraindicated),

OR

- **At progression** - Treated Patient
 - For patients progressing on or after chemotherapy or immunotherapy who have never been tested for EGFR SNVs and indels; rearrangements in ALK and ROS1; and SNVs for BRAFs, and for whom tissue-based CGP is infeasible (i.e., quantity not sufficient for tissue-based CGP from original biopsy); **OR**
 - For patients progressing on any tyrosine kinase inhibitors (TKIs).

If no genetic alteration is detected by Guardant360®, or if circulating tumor DNA (ctDNA) is insufficient/not detected, tissue-based genotyping should be considered.

Summary of Evidence

It is estimated that more than 222,500 new cases of lung cancer will be diagnosed in the United States (US) this year.¹ This represents roughly 13% of all new cancer diagnoses and 26% of cancer deaths.¹ At least 87% of lung cancer is NSCLC.² The estimated 5-year survival rate for all NSCLC cancer patients is 17%, and only 4% for patients with advanced stage IIIB/IV disease.³

The pathophysiological development of lung cancer is complicated, with several known genomic alterations found individually or in combination in many patients. These alterations may be due to toxic exposure or underlying genetic factors, and not all alterations have the same impact on disease development or prognosis. Some alterations appear to be integral to the transformation and ongoing growth of the tumor (driver alterations). Among the best studied in this class are EGFR SNVs and indels and EML4-ALK rearrangements/fusions. EGFR-mutated NSCLC comprises up to 15% of all NSCLC patients in the US, with higher prevalence in certain ethnic groups (e.g., 40% in Asian Americans and 26% in Latin Americans).⁴ These mutations convey a more favorable prognosis and predict response to treatment with oral EGFR inhibitors such as erlotinib, gefitinib, or afatinib. Similarly, rearrangements of ALK and EML4 or other less common fusion partners occur in approximately 4% of all NSCLC patients and predict response to treatment with oral ALK-targeted inhibitors such as crizotinib, ceritinib, or alectinib.⁵

Genomic alterations in NSCLC vary by smoking history, ethnicity and age. Sequencing of tumor specimens in never-smokers has shown a higher mutation frequency of EGFR than in smokers, with some non-smoking ethnic groups such as Asian women having a much higher mutation frequency than their Caucasian counterparts.⁶ Prevalence of ALK rearrangements is also higher in non-smokers.⁶ In contrast, smokers have a higher prevalence of targetable alterations in the MET and BRAF genes.⁷⁻⁹

Traditionally, tumor genotyping has been conducted by direct interrogation of tumor tissue obtained through invasive tissue sampling procedures. This diagnostic approach, however, is limited by the availability of sufficient tumor tissue and the ability of patients to undergo invasive procedures. In a recent study of over 100 community-based oncologists, nearly one-third of NSCLC patients were not tested for EGFR or ALK, over 75% were not tested for ROS1 fusions, and fewer than 10% were tested for all guideline-recommended alterations.⁶ These results were similar to a study in a single academic center where only 58% of non-squamous NSCLC were tested for EGFR and 40% for ALK fusions, despite 13% of patients undergoing repeat invasive biopsies to obtain sufficient tissue for genomic testing.⁷ Tissue availability was similarly limited in several recent series, some of which reported that more than 50% of NSCLC patients had insufficient or unobtainable material for tissue-based CGP.⁸⁻¹⁰

Even when successful, tissue acquisition procedures pose a significant morbidity and mortality risk to Medicare patients. In a recent report, 19% of all lung tissue acquisition procedures resulted in a serious adverse event,¹¹ while the National Lung Cancer Screening Trial reported 1-2% mortality rates in their cohorts.¹² Given the high rates of inadequate genotyping described above, plasma-based CGP can provide an opportunity for non- and under-genotyped patients to benefit from matched therapy. Preliminary studies suggest that plasma-based CGP can identify potential genomic targets in both the first and second lines, with response rates similar to those of patients identified using tissue-based CGP and tissue-based companion diagnostics (CoDx).^{9,10,13-15}

Currently, a variety of techniques are used to test for these genomic alterations in plasma specimens to determine if a patient is a candidate for targeted therapy, including the FDA-approved Cobas® EGFR Mutation Test (tissue or plasma samples) for erlotinib and osimertinib, which interrogates specific regions in EGFR to determine whether the genomic alteration of interest is present. For various reasons, these CoDx and other existing LDT techniques may miss deleterious EGFR mutations, ALK rearrangements, and other genomic alterations that can be targeted with FDA-approved drugs, though efficacy data for the patient's specific indication may be limited. For example, alterations may occur outside the sequenced region or involve complex alterations (e.g. indels, copy number alterations, or rearrangements) that are not detectable by certain tests.²⁰ Newer techniques such as next-generation sequencing (NGS), offer the possibility of not only increased analytical sensitivity but also the ability to detect a broader range of genomic alterations.¹⁶

Unlike traditional tissue-based CGP, plasma-based CGP is complicated by the biology of the ctDNA analyte. Foremost among these challenges is the median variant allele fraction (VAF) of somatic variants. In contrast to tissue, where tumor DNA can be highly represented and somatic VAFs are generally 10-80%, ctDNA is typically greatly diluted by non-neoplastic cell-free DNA (cfDNA), resulting in a median somatic VAF of 0.4% and median total ctDNA tumor burden of 1%.¹⁷

Clinically, plasma-based CGP can help patients avoid an invasive biopsy to obtain tissue for tumor genotyping. This situation may arise at diagnosis or at progression when tissue-based CGP/CoDx is infeasible (i.e., quantity not sufficient or invasive biopsy is medically contraindicated). Plasma-based CGP may help avoid invasive biopsies for tissue acquisition if either a valid treatment target (e.g., EGFR L858R) or a mutually exclusive driver (e.g., KRAS G12V) is identified. For those patients in whom plasma-based CGP does not identify such "clinically actionable" alterations, follow-up invasive tissue biopsy is indicated, consistent with the approach articulated in the indications for use for the recently approved Cobas® EGFR Mutation Test v2 (P150047).

Use of one plasma-based CGP assay, Guardant360®, has been shown to identify targetable genomic alterations in patients when tissue was insufficient or unobtainable for genotyping. In a prospective study by Lee et al., Guardant360® identified targetable EGFR or ALK alterations in 17 of 72 consecutive advanced NSCLC patients with insufficient specimen for tissue-based CGP, either at presentation or at progression.¹⁵ The objective response rate (RECIST 1.1) to targeted therapy in this population was 87% and the disease control rate was 100%. Of note, an EML4-ALK fusion was detected in the 2nd line of therapy and an EGFR L858R mutation was detected in the 3rd line of therapy, highlighting that local non-CGP testing may miss targetable driver mutations in the 1st line.

Similarly, in a second study by Rozenblum et al., tissue biopsies from 101 advanced NSCLC patients were tested locally for EGFR mutations and ALK fusions.¹⁴ Tissue-based CGP identified 15 EGFR and ALK alterations missed locally, but could only be performed in 82 of the 101 (81%) patients because of tissue exhaustion. Guardant360® was used in the 19 remaining patients and two (11%) additional sensitizing EGFR mutations were found that had been missed with local tissue genotyping. In addition, alterations including MET amplification, ERBB2 (HER2) mutation, and two RET fusions were also identified (missed with local non-CGP genotyping), for a total of 6 driver alterations in 19 patients (32%). Thus, Guardant360® changed treatment in 32% of patients with insufficient samples for tissue-based CGP, with five receiving matched therapy. These five patients achieved a 60% objective response rate and 100% disease control rate.

Guardant360® has demonstrated targeted therapy response rates similar to tissue-detected genomic targets in seven different published NSCLC studies.^{9,10,13-15,19,20} Additionally, Thompson et al. and Villaflor et al. demonstrated similar findings and experience in their series of 102 and 51 patients, respectively.^{9,10} Additionally, Santos et al. reported a series utilizing Guardant360® in 81 advanced NSCLC patients in which ten patients with EGFR alterations were identified that were not discovered by tissue testing, over half of which were in the untreated setting.²⁰ These findings are consistent with additional studies indicating that the Guardant360® assay can identify treatment opportunities missed by some tissue-based approaches.^{10,13,19}

A summary of the AV and CV tables is available from this contractor.

Professional Society Clinical Practice Guidelines

National Comprehensive Cancer Network (NCCN) NSCLC clinical practice guidelines (v5.2017) recommend "broader molecular profiling with the goal of identifying rare driver mutations for which effective drugs may already be available, or to appropriately counsel patients regarding the availability of clinical trials." Broad molecular profiling is "a key component of the improvement of care of patients with NSCLC" and includes at least seven genes with alterations targetable with FDA-approved drugs: EGFR and ERBB2 point mutations and indels; BRAF mutations; ALK, ROS1, and RET rearrangements; and MET amplification and deletion/skipping of exon 14.²¹ (Note that all recommendations are category 2A, indicating "uniform" (i.e., ≥ 85%) consensus based on "lower-level evidence", except ERBB2, which is 2B, representing 50-85% consensus based on "lower-level

evidence".) These guidelines also state "if tissue biopsy is not feasible, plasma biopsy should be considered" and that "if plasma biopsy is negative, then tissue biopsy is recommended if feasible".²¹

Guardant360® Test Description and Intended Use

Guardant360® analyzes tumor-derived cell-free DNA (also known as ctDNA) to detect somatic alterations that, in conjunction with standard clinical assessment, can guide treatment decisions in the following intended use population: patients with Stage IIIB/IV NSCLC

- **At diagnosis (Untreated Patient)** - when results for EGFR SNVs and indels; rearrangements in ALK and ROS1; and SNVs for BRAF are not available AND when tissue-based CGP is infeasible from original biopsy specimen (i.e., quantity not sufficient for tissue-based CGP or invasive biopsy is medically contraindicated); OR
- **At progression (Treated Patient):**
 - For patients progressing on or after chemotherapy or immunotherapy who have never been tested for EGFR SNVs and indels; rearrangements in ALK, and ROS1; and SNVs for BRAF and for whom tissue-based CGP is infeasible (i.e., quantity not sufficient for tissue-based CGP); OR
 - For patients progressing on any TKIs.

If no alteration is detected by Guardant360® or if ctDNA is insufficient/not detected, tissue-based genotyping should be considered.

Guardant360® detects the following classes of alterations:

- Base pair substitutions (also known as SNVs);
- Small (≤ 20 bp) and large (> 20 bp) indels;
- Copy number amplifications (CNAs); and
- Rearrangements.

The analytical performance characteristics of Guardant360® are consistent with MolDX's Analytical Performance Specifications for Qualitative Tumor-only Somatic Variant Detection using Circulating Tumor DNA (M00135), and will be detailed elsewhere.

Criteria for Coverage

Guardant360® is covered only when the following conditions are met:

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

or

- Patient is progressing on or after chemotherapy or immunotherapy and has never been tested for EGFR SNVs and indels; rearrangements in ALK, and ROS1; or SNVs for BRAF, **and** tissue-based CGP is infeasible (i.e. quantity not sufficient for tissue-based CGP); or
- Patient is progressing on any TKIs

Analysis of Evidence (Rationale for Determination)

Level of Evidence

Quality: Moderate
Strength: Limited
Weight: Limited

The clinical utility of Guardant360® testing for patients with advanced NSCLC at diagnosis or at progression, as defined in the intended use above, is quite promising. This contractor believes that forthcoming prospective clinical studies in these patients will demonstrate improved patient clinical outcomes.

Continued coverage for Guardant360® testing is dependent on annual review by this contractor of such data and publications.

[Back to Top](#)

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes

Group 1 Paragraph: N/A

Group 1 Codes:

81479 UNLISTED MOLECULAR PATHOLOGY PROCEDURE

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph: N/A

Group 1 Codes:

ICD-10 Codes

Description

C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung

ICD-10 Codes	Description
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C38.1	Malignant neoplasm of anterior mediastinum
C38.2	Malignant neoplasm of posterior mediastinum
C38.4	Malignant neoplasm of pleura
C38.8	Malignant neoplasm of overlapping sites of heart, mediastinum and pleura

ICD-10 Codes that DO NOT Support Medical Necessity N/A

ICD-10 Additional Information [Back to Top](#)

General Information

Associated Information

N/A

Sources of Information

N/A

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[Back to Top](#)

Revision History Information

N/A [Back to Top](#)

Associated Documents

Attachments N/A

Related Local Coverage Documents Article(s) [A56092 - Response to Comments: MolDX: Guardant360® Plasma-Based Comprehensive Genomic Profiling in Non-Small Cell Lung Cancer \(NSCLC\)](#) LCD(s) [DL37651 - MolDX: Guardant360® Plasma-Based Comprehensive Genomic Profiling in Non-Small Cell Lung Cancer \(NSCLC\)](#)

Keywords

- Guardant360
- MoIDX
- Non-Small Cell Lung Cancer
- NSCLC
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- lung cancer
- CGP
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