

Non-small Cell Lung Cancer (NSCLC) Biomarker Testing

Guide for Advanced Practice Providers



Cancer biomarkers are¹:

- Genes, proteins, and other substances on tumors that can provide information about certain cancers

Types of NSCLC biomarkers^{2,3}:

- Gene alterations (mutations or fusions), also called driver mutations
 - *ALK, BRAF, EGFR, ERBB2 (HER2), KRAS, MET, NTRK, RET, ROS1*
- Immune biomarker
 - PD-L1



Biomarker testing is important because¹:

- It assists with appropriate treatment selection, including targeted therapies, that may be clinically beneficial to patients with NSCLC

Biomarker testing may be appropriate⁴:

- When lung cancer is suspected
- At diagnosis of lung cancer
- At lung cancer recurrence or progression post-treatment

Alternative names for biomarker testing^{4,5}:

- Genomic, molecular, mutation, somatic, tumor, tumor genetic, or tumor marker testing
- Genomic or molecular profiling
- Genome sequencing, next-generation sequencing
- Tumor subtyping

Barriers to biomarker testing access⁶:

- Lack of clinician and patient awareness
- Inadequate insurance coverage
- Out-of-pocket costs



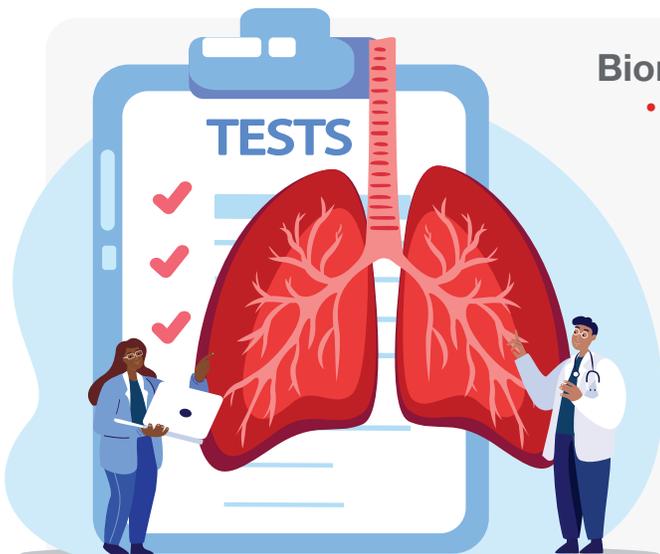
For biomarker testing and/or financial assistance resources, scan the QR code



Comprehensive biomarker testing^{1,7}:

- Can simultaneously detect a broad spectrum of driver mutations
- Patients who have not undergone complete biomarker testing may receive suboptimal therapy

When feasible, biomarker testing should be performed via a broad, panel-based approach, typically done by next-generation sequencing⁷



Biomarkers can be measured by⁸⁻¹⁰:

- Tissue or liquid biopsies (eg, blood or other bodily fluids)
 - Tissue testing is recommended, but liquid biopsies can be considered when tissue sampling is unattainable or insufficient
- Tissue and liquid biopsies can produce false-negative results, supporting the need for concurrent tissue and liquid biopsy testing to increase the likelihood of actionable alteration detection and time to treatment reduction

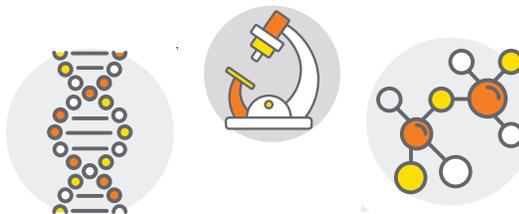
Biomarker test results may help to⁵:

- Determine whether the cancer is progressing
- Predict the likelihood of a cancer growing and spreading quickly or slowly
- Select the therapy most likely to result in a favorable response

If clinically feasible, biomarker testing results for actionable oncogenic mutations should be known before initiating immune checkpoint inhibitor therapy in eligible patients with advanced NSCLC^{11,12}

Targeted therapies for NSCLC²:

- Identify and attack specific proteins on NSCLC cells
- May also be referred to as:
 - Biomarker-driven therapies
 - Precision medicines
 - Molecularly targeted drugs or therapies



Targeted therapies have been shown to decrease tumor burden, including some symptoms, and improve the quality of life for patients with NSCLC and specific tumor biomarkers^{13,14}

NSCLC biomarkers and approved targeted therapies¹⁵⁻¹⁸

NSCLC Biomarker	Approved Targeted Therapies
ALK	Alectinib, brigatinib, ceritinib, crizotinib, lorlatinib
BRAF	Binimetinib + encorafenib, dabrafenib + trametinib
EGFR	Afatinib, amivantamab-vmjw, dacomitinib, erlotinib, gefitinib, necitumumab, osimertinib
ERBB2 (HER2)	Fam-trastuzumab deruxtecan-nxki
KRAS	Adagrasib, sotorasib
MET	Capmatinib, tepotinib
NTRK1/2/3	Entrectinib, larotrectinib
PD-L1	Atezolizumab, durvalumab
RET	Pralsetinib, selpercatinib
ROS1	Crizotinib, entrectinib, repotrectinib

Recommended treatment for patients with metastatic NSCLC and specific biomarkers is targeted therapy, regardless of PD-L1 levels^{11,12}

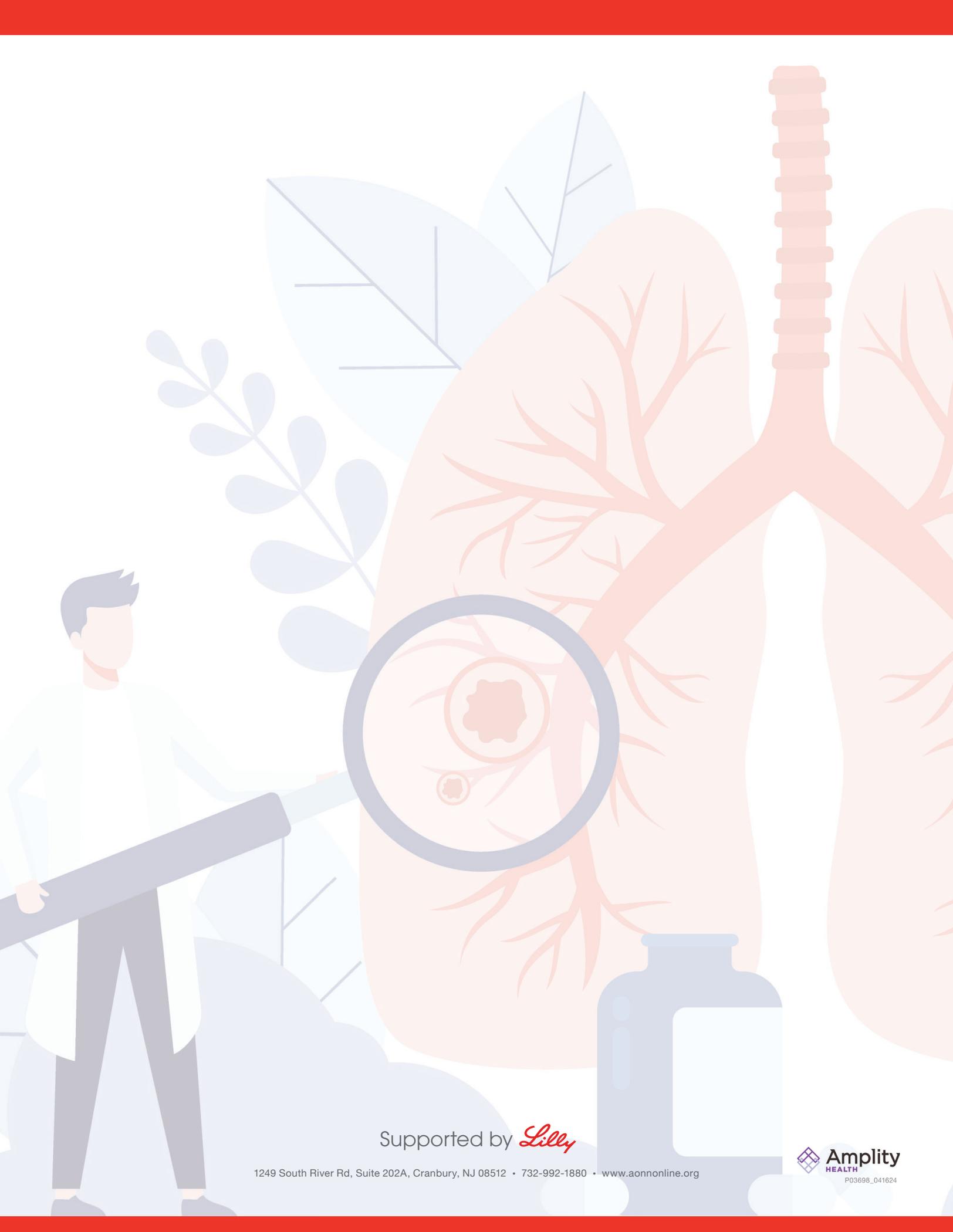
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