CHEAT SHEET

Biomarker Testing in Oncology

Understanding a cancer patient's genetic profile to help guide appropriate treatment selection

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Key takeaways

- Biomarker testing (also known as mutation, genomic, or molecular testing) uses laboratory tests to help the health care team gather as much information as possible about a patient's cancer and uncover whether the patient has an actionable driver mutation. [1]
- Biomarker testing can help providers make more informed treatment decisions based on a patient's genomic makeup.[1] Additionally, biomarker testing can align with a health system's broader strategic goals (e.g., precision medicine).

Source: 1. "Biomarker Testing," LUNGevity;

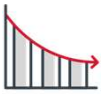
What is biomarker testing?

A **biomarker** is a characteristic that can be scientifically measured or evaluated as an indicator of normal biologic processes, disease, or response to therapeutic intervention.[1] The major types of biomarkers include molecular, histologic, radiographic, and physiologic characteristics.[1] Examples of biomarkers include blood pressure, blood glucose levels, and imaging results.[1] As the field of precision medicine grows, the focus on genetic biomarkers has grown as well. The following sections will focus on biomarker testing in oncology.

Biomarker testing (also known as mutation, genomic, or molecular testing) uses laboratory tests to help the health care team gather as much information as possible about a patient's cancer and uncover whether the patient has an actionable mutation.[2] Four categories of biomarker testing include: predisposition, diagnostic, prognostic, and predictive:[3]

Predisposition: A certain genetic biomarker could indicate an increased risk or susceptibility to a given disease [3]

Diagnostic: Distinguish between health and disease [3]



Prognostic: Indicates how a disease may develop after a diagnosis and may be useful in treatment selection, but does not directly predict the response to a treatment[3]

Predictive: Predict an outcome following an intervention (e.g., response or lack of response to drug) [3]

A companion diagnostic (**CDx)** is typically an in vitro diagnostic that detects a predictive biomarker to determine the likely efficacy and safety of a corresponding drug or biological product.[4] For example, FoundationOne® CDx is an FDA-approved, tissue-based broad CDx that physicians can use to analyze the genomic profile of individual patient's tumors. Results may help inform treatment decisions for over 20 FDA-approved targeted therapies.[5] Clinicians should order the corresponding CDx to determine appropriate therapeutic options for each patient.

Source: 1. "Biomarker Terminology: Speaking the Same Language," US Food and Drug Administration; 2. "Biomarker Testing," LUNGevity; 3. "Types of Biomarkers," Personalized Medicine Coalition; 4. "Companion Diagnostics," US Food and Drug Administration; 5. "What is FoundationOne® CDx?," Foundation Medicine.

Why does biomarker testing matter?

Biomarker testing can help providers make more informed treatment decisions based on a patient's genomic makeup or the genomic makeup of their cancer. Additionally, biomarker testing can align with a health system's broader strategic goals. For example, with the shift to value-based care, many organizations are focused on delivering appropriate, high-value care. Additionally, many organizations are focused on expanding their precision medicine programs to provide patients with more informed, personalized care. Biomarker testing aligns with each of these system-level strategic priorities.[1]

Given the advantages of biomarker testing, the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend assessment of biomarker test results prior to treatment initiation in eligible patients with metastatic non-small cell lung cancer (mNSCLC).[2] As a result, biomarker testing is essential to provide guideline-concordant care in many areas of oncology.

Despite these benefits, gaps still exist in realizing the full potential of biomarker testing. Many patients who are eligible for biomarker testing do not receive guideline recommended testing.[1] Of patients who do receive biomarker testing, many eligible patients do not receive targeted therapy due to challenges throughout the process (e.g., insufficient tissue, long turnaround times that prevent clinicians from using results to help inform treatment decisions, complicated or inaccessible test reports).[1]

Benefits of genetic biomarker testing

37.6%

of cancer patients in one study had **actionable genetic mutations** meaning they could be matched to existing drugs[3]

Improvement opportunities

55%

of patients with **actionable mutations** in one study did NOT receive targeted therapy[4]

21%

of North American-based oncologists made treatment **decisions before the patient's genetic mutation results were available**[5]

Source: 1. Data on File, DoFP US-57118, AstraZeneca Pharmaceuticals LP; 2. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer. v.5.2021. © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed July 8, 2021. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. The NCCN Guidelines® for NSCLC provide recommendations for certain individual biomarkers that should be tested and recommend testing techniques but do not endorse any specific commercially available biomarker assays or commercial laboratories. 3. Flaherty K, et al. "Molecular Landscape and Actionable Alterations in a Genomically Guided Cancer Clinical Trial: National Cancer Institute Molecular Analysis for Therapy Choice (NCI-MATCH)," Journal of Clinical Oncology, doi: 10.1200/JCO.19.03010, 2020; 4. Gierman H, et al. "Genomic testing and treatment landscape in patients with advanced non-small cell lung cancer (aNSCLC) using real-world data from community oncology practices," Journal of Clinical Oncology, 2019, doi: 10.1200/JCO.2019.37.15_suppl.1585; 5. Mason C, et al. "Patterns of Biomarker Testing Rates and Appropriate Use of Targeted Therapy in the First-Line, Metastatic Non-Small Cell Lung Cancer Treatment Setting," Journal of Clinical Pathways, 2018, doi:10.25270/jcp.2018.02.00001.

How does it work?

No two patient journeys look the same--especially in cancer care. However, the biomarker testing process does follow a general order of operations:[1]

#1 Determine if biomarker testing is appropriate

- Clinician extracts a sample for testing
- Pathologist tests initial tissue sample to diagnose and stage the cancer
- Pathologist sends tissue results back to referring clinician
- Based on the diagnosis and staging, the referring clinician will then refer the patient to a medical oncologist or surgeon
- Medical oncologist will discuss patient's case during tumor board and determine if biomarker testing is appropriate

#2 Run appropriate test, analyze results, implement recommendations

- Medical oncologist will order biomarker testing if not initiated automatically by pathologist. Testing either uses existing tissue sample from previous biopsy or takes a new sample because of insufficient tissue (can be either tissue or liquid)
- Pathologist sends sample to lab (either external vendor or in-house lab) who tests the sample with the most appropriate testing method
- The lab identifies and compiles relevant genetic information in a report and sends back to referring provider
- Pathologist/administrative staff at the provider organization enter report into the system's EHR (or automatically uploaded into EHR)
- Medical oncologist reviews and analyzes results
- Medical oncologist can bring results to molecular tumor board (if available) for further discussion and treatment recommendations
- Provider makes informed treatment decision based on biomarker information and educates patient on results and treatment initiation

Source: 1. "Optimizing Oncology Care Through Biomarker Adoption," IQVIA, 2020.

Conversations you should be having with your *leadership team*

01 Have you considered how biomarker testing can support our broader organizational goal of delivering high-value, appropriate care?

02 What are long-lasting, sustainable investments we can make in our biomarker testing process to support our push to precision medicine?

03 How can we standardize biomarker testing across our broader organization?

04 What internal resources (e.g., EHR, staff) can we leverage to improve our biomarker testing process?

Conversations you should be having with your *frontline staff*

01 What challenges do you run into when it comes to biomarker testing? What do you think works well?

02 How can we standardize our biomarker testing process across all our clinicians and sites?

03 How can we codify our processes and procedures to facilitate widespread adoption of those standards?

04 How can we broadly communicate the value of biomarker testing and provide updates on changing guidelines throughout our sites?

About this research

The research in this document is based on Advisory Board's original research and analysis of literature and primary research interviews with health care executives, clinicians, and stakeholders in the biomarker testing process. It does not reflect the opinions or suggestions of AstraZeneca.

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