

A Financial Advocate's Guide to Biomarker Testing in Cancer

What is Biomarker Testing?

Patients with cancer often undergo **biomarker testing** to determine if a targeted therapy may be an effective treatment option. Biomarkers may include things like genes, proteins, and other molecular targets.

When patients receive medical treatment based on their biomarker test results, this is called **precision medicine**.

Biomarker testing may also be called:

- Molecular testing or profiling
- Tumor testing or profiling
- Genetic or genomic testing or profiling
- Next-generation sequencing (NGS)
- DNA or RNA sequencing

Companion Diagnostic

When targeted therapies require a specific biomarker test to provide important information related to the therapy, the test is called a **companion diagnostic**. Companion diagnostic tests are sometimes required before insurance companies will approve therapy.



TIP: Confused about these terms? Cancer care programs can follow the recommendations outlined on commoncancertestingterms.org when discussing biomarker testing (and to clearly differentiate tumor biomarker testing from genetic testing for an inherited mutation).

A Few Examples of Cancer Biomarkers and Associated Targeted Therapies:

Type of Cancer*	Biomarker	Therapy
Non-small cell lung cancer (NSCLC)	EGFR	Oral EGFR inhibitor
Many solid tumors, including triple-negative breast, cervical	PD-L1	Immune checkpoint inhibitor
Melanoma	BRAF	Oral BRAF inhibitor
Breast	HER2	HER2 inhibitor
Solid tumors	NTRK	Oral NTRK inhibitor
Ovarian, breast	BRCA	Oral PARP inhibitor
Solid tumors; most frequently colorectal, endometrial	MMR Deficiency (dMMR)	Immune checkpoint inhibitor

*Only selected tumor types and therapy may be listed for each biomarker; please consult the current product labeling for the most up-to-date information

Next-Generation Sequencing (NGS)

Next-generation sequencing (NGS) is a common technique used to perform cancer biomarker testing. In 2018, the Centers for Medicare and Medicaid Services (CMS) determined that **national coverage for NGS testing** would be available for patients with advanced cancers.

In 2022, the American Society of Clinical Oncology (ASCO) released a **Provisional Clinical Opinion** recommending NGS-based biomarker testing in patients with metastatic or advanced cancers to guide the use of treatments that may target specific biomarkers.



TIP: Remember that NGS is a testing technique and not a specific biomarker test. NGS allows for multiple biomarkers to be assessed as part of one test.

Prior Authorization

Prior authorization is often needed when ordering biomarker testing. To reduce the risk of insurance denial, prepare all of the required documentation (e.g., histology, clinical stage, and provider documentation). In some cancer programs, a biomarker navigator (or similar role) may enter all the required prior authorization information when placing the test order.



TIP: Consider what national resources are available based on patient type. For example, **Paying for Biomarker Testing**, a resource created by ACCC and LUNgevity, offers a helpful guide for patients with lung cancer who are receiving biomarker testing.

acc-cancer.org/paying-biomarker-testing

Financial Assistance Programs

Patients may experience high out-of-pocket expenses for biomarker testing. In some cases, insurance companies may not cover the cost of testing (e.g., the test is considered experimental or investigational, or the plan does not cover the cost of cancer treatment). Fortunately, many reference laboratories that perform biomarker testing offer patient assistance. Check vendor websites for financial assistance programs and eligibility requirements.



TIP: Remind patients that they may receive an Explanation of Benefits (EOB), and that this is not a medical bill.

Ordering Multiple Tests

While biomarker tests are often ordered at the time of cancer diagnosis, some patients may undergo biomarker testing to see if a new tumor mutation is causing them to be resistant to their prescribed targeted therapy. Other patients may undergo repeat testing to determine how their tumor is responding to treatment. In some cases, an oncologist may order a biomarker test on the diagnostic biopsy tissue and another biomarker test on a collected blood sample. While many insurance companies will cover the cost of one test, they may not cover multiple tests.



TIP: Check to see if the reference laboratories offer financial assistance for repeat testing.

Patient Education

It is critical to provide education to patients about the purpose and clinical importance of biomarker testing. Patients may be easily confused about different types of genetic tests that are marketed to the public. Cancer biomarker tests are not the same as at-home or over-the-counter (OTC) genetic tests. Some OTC DNA and hereditary tests are used to identify ancestry and/or cancer risk factors and may cost a few hundred dollars. In contrast, a cancer biomarker test is performed on a patient who is diagnosed with cancer to aid in diagnosis, staging, and treatment, and may cost several thousands of dollars.



TIP: Read the ACCC resource on **Talking to Your Patients About Biomarker Testing in Cancer Care**. Then, use **ACCC's Conversation Guide: Biomarker Testing and its Role in Cancer Care**, to help guide discussion with patients on frequently asked questions related to biomarker testing.

acc-cancer.org/biomarker-provider-guide

Optimizing Coordination and Communication

Biomarker tests are often ordered by medical oncologists or pathologists. Some may be ordered by surgeons or by physicians performing the initial diagnostic biopsy. Here are some ways that financial advocates may be able to proactively reduce patient stress about biomarker testing:

- Remind physicians to inform patients about financial assistance programs offered by reference laboratories.
- Ask reference laboratories if they would provide regular updates on which patients have applied for financial assistance and the status of those applications.
- Develop a patient education brochure that explains the clinical importance of biomarker testing and how they can apply for financial assistance.
- Create a folder of journal articles and templated appeal letters to be prepared to dispute insurance company denials.

As more patients with cancer undergo biomarker testing, financial advocates play a key role in ensuring that patients receive optimal care while minimizing the risk of experiencing financial toxicity.

Learn more at acc-cancer.org/precision-medicine-stewardship. Developed in partnership with AONN+ and ASCP.

This project is made possible by support from AstraZeneca and Blueprint Medicines.