

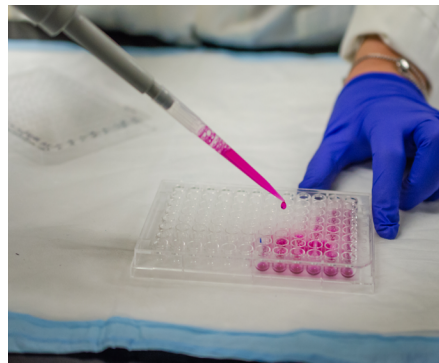


## WHY IS BIOMARKER TESTING IMPORTANT?

- Biomarker testing may improve outcomes for people with cancer, particularly those with digestive, lung, and breast cancers.
- It is common for targeted therapies to require patients to have biomarker testing. Out of all cancer drugs approved in the last five years, almost 60% suggest biomarker testing before use.
- Biomarkers can provide doctors with clues about how patients will react or respond to standard treatment options and help guide treatment decisions.
- Biomarkers and targeted therapies are driving more cancer clinical trials.

### BIOMARKER TESTS

A biomarker test analyzes tissue or blood samples for the presence of specific differences that can provide insights into diseases like cancer. Medical treatment can be guided by biomarker testing, often called precision medicine. By identifying these biomarkers, cancer patients may be able to receive treatments they might not otherwise receive.



## WHY KNOWING YOUR BIOMARKER PROFILE IS IMPORTANT

How can you know you are making the best treatment decision? Your “biomarker profile” is an important piece of information for you and your medical team to weigh the benefits and risks of different treatment options and choose an option that is most likely to be effective for you. Personalizing treatment based on your specific tumor profile may result in better clinical outcomes and reduce the possibility of trying ineffective treatments.

## WHAT TREATMENT OPTION IS THE BEST FOR YOU?

Determining treatment options for your cancer is a shared decision between you and your healthcare team. It is up to you to decide what role you would like in your treatment decisions. Biomarker testing results are considered with the best current medical evidence available to determine options to treat your cancer.

1. Standard treatment is the currently accepted evidence-based treatment option for certain types of disease.
2. Some cancers include standard-of-care treatments which may integrate a combination of therapies such as chemotherapy, radiation therapy, immunotherapy, targeted therapy, and surgery.



Before beginning treatment, you may want to seek a second opinion. A doctor other than your current doctor will review your medical records and give an opinion about your diagnosis and potential treatments. The second doctor’s opinion may or may not suggest a different approach to your care. A second opinion can help you feel more comfortable when deciding on a treatment plan.



### How Your Biomarker Profile Affects Access to Therapy

When the RNA or DNA sequence of a cell changes, this is known as a mutation. Mutations can lead to changes in the way cells function, which can sometimes lead to cancer. Currently, every identified mutation does not have an approved therapy.

If you have been diagnosed with cancer, your oncologist may recommend that you undergo biomarker testing which will identify fusions, amplifications, and immunologic parameters in your cells. The results of your genomic testing help ensure various treatment options may be considered. Your oncologist will coordinate with a pathologist who will perform and interpret the biomarker testing. It can take time for testing to be completed, so there may be a two to three-week delay in receiving your test results.

Progress is being made towards developing therapies that target specific mutations, fusions, and amplifications known to play a role in cancer growth. One reason this approach is becoming widely utilized is the hope that such targeted therapies might be more effective than other treatments such as chemotherapy. It is important to note that sometimes these targeted treatments may not be covered by insurance without biomarker testing.

Once testing is complete, there is a chance your molecular profile leads to a recommendation of a treatment that does not have an FDA-approved indication for your diagnosis although the treatment is commercially available and FDA-approved for other cancers. This is known as an “off-label” indication.

Using a drug off-label for cancer treatment is not unusual, and insurance companies may pay for off-label use as long as 1) the drug is listed on the drug formulary for your insurance plan and 2) the off-label use is listed in an approved drug compendium based on clinical research that supports the use of the drug for other indications. If this situation applies to you, it can affect payment by your insurance company. If you are denied coverage of a medication because it is an off-label indication, ask your doctor to provide documents to the insurance company supporting the use of the medication. Patient Advocate Foundation is here to help with appealing the denial and obtaining the off-label medication.



Patient Advocate Foundation can help you address financial or insurance barriers you face with gaining access. Click this link to view our full-length guide entitled **Getting the Right Test at the Right Time: A Cancer Patient's Guide to Biomarkers**. References for all Biomarker Tip Sheets can be found [here](#).

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