

# Biomarker Testing: Allowing Individualized Treatment for Cancer Patients



By Sakeer Hussain, MD

**Biomarkers are predictive markers in genetic material that can indicate which medications might work for a given patient. For cancer patients, biomarker testing is an important first step toward tailored treatment.**

Researchers may not have cured cancer yet, but advances in technology and medical science have already helped cancer mortality drop significantly — even as instances of cancer have increased dramatically.<sup>1</sup> These advances are in part due to precision cancer treatment, which uses a patient's genetics to pinpoint the most effective treatment.

Biomarkers, also called molecular markers or signature molecules, are biological factors found in blood, body fluids or tissues that indicate normal or abnormal cell processes and even the presence of a specific condition or disease. A biomarker can be used to predict how a person's body will respond to a specific treatment based on the outcomes of other patients with similar biomarkers.<sup>2</sup>

Biomarker tests for cancer help oncologists determine the best method of treatment based on what has proven most effective for that marker. Health care providers can also learn more about the patient and his or her condition, specific type of cancer, stage of cancer and cancer growth pattern. With these details, providers can develop a targeted treatment path.

Biomarker testing brings a new dimension to personalized medical care. These tests are not, however, always available to patients.<sup>3</sup>

# How Biomarker Testing Supports Patient-Centered Care

There are multiple methods of biomarker testing.

Some require a tumor biopsy, while others require a liquid biopsy or blood sample. Certain tests also call for healthy cells for baseline comparison. Some tests look at genes in the cancer, some explore the DNA, and others consider physical changes in the tumor.

Whatever form they take, these tests can inform providers about a patient's predisposition for cancer, identify molecular makeup, pinpoint the most beneficial treatment, monitor the body's response to early treatment, and track the speed of growth or spread of disease.

**Perhaps the greatest benefit of biomarker testing, however, is the certainty and specificity of diagnosis.** Testing is a part of precision medicine, an approach that has gained traction over the past two decades. The approach focuses on customizing treatment for specific patients rather than taking a "one-size-fits-all" strategy.

In recent years, technological advancement has made tailored treatment increasingly practical, and researchers and clinicians continue to refine their practice of precision medicine.

## Biomarker testing allows for a new level of individualization.

Testing also spares patients from undergoing treatments that are unlikely to work. Biomarkers can indicate, for example, whether chemotherapy is a viable treatment option or if there are better alternatives. This allows patients who would benefit from a targeted cancer medication to bypass the painful side effects of chemotherapy.

Access to biomarker testing is not universal, but testing is typically suggested for recurrent cancers, as well as for breast cancer, colorectal cancer and some lung cancers. Researchers will continue to identify more markers and determine which treatments correspond with each marker — or at least identify a place to start treatment and a roadmap. Many oncologists believe that most cancers, along with many other diseases, would be best treated with the aid of biomarker testing.

## The Need for Increased Awareness

**Precision medicine continues to grow at an astonishing pace, with biomarkers discovered almost daily.** While that's exciting for cancer care, it can be difficult for providers to stay on top of the latest testing. A key barrier is often the simple fact that clinicians may not be up to date on currently available tests and biomarkers.

The gap in awareness impacts some communities more than others. In a study of oncologists who treat non-small cell lung cancer, community-based physicians were 26% less likely

to order biomarker testing for the initial biopsy than were those in an academic setting. And only 40% of patients of low socioeconomic status were proactively offered biomarker tests.<sup>4</sup>

Outreach and education for both clinical oncologists and community-based physicians, therefore, is essential. So is standardizing the language and terminology used to discuss biomarker testing and related treatments, which can be confusing for patients and even providers.



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## Coverage, Delays and Cost Barriers

Beyond general awareness of biomarker testing, several other challenges can present barriers. Those challenges include: lacking a sufficient tumor sample for testing purposes, the disease being in an early stage, treating a patient who is not healthy enough to undergo a test, and the patient's cost for testing or for the treatments that follow.<sup>5</sup>

**While many patients obtain biomarker testing without issue, not all insurers offer ready or complete coverage.** Under Medicare, for example, coverage may depend on cancer type and prognosis.

Meanwhile, insurers may not be able to keep up with the ever-changing technology. Many insurance companies that use evidence-based medicine to determine payments don't cover broad panel tests. Some will offer coverage for testing one or two biomarkers but consider a broad test to be experimental medicine.

Delays can present another challenge. Medicare's billing policies require that providers wait two weeks after sample collection for testing.

Then testing itself can take time. Of course, for cancer patients, every second matters. Time spent waiting for answers and treatment is time that impacts a patient's condition and potentially allows for their cancer to grow or spread.

Out-of-pocket costs can also pose a barrier to patients. Even if patients' insurers cover the cost of biomarker testing, they may not offer comparable coverage for treatment.

This is especially likely if the results show that a patient is a candidate for an innovative, targeted cancer medication. Patients may find themselves in the difficult situation of knowing a cancer medication would work for them but not being able to manage the out-of-pocket cost.

## Rapid Innovation & Patchwork Standards

Challenges with biomarker testing also arise from the patchwork of standards that exist not just among insurers, but all along the way, from the research laboratory to the clinician's office.

New biomarkers are discovered constantly, new tests are developed at regular intervals, and real-world outcomes are added to the existing data every day. As a result, managing the research and real-world data has created a bottleneck in regulatory and insurance processes. Electronic health records and laboratory information systems are often unable to capture and integrate this information efficiently.

The Committee on Policy Issues in the Clinical Development and Use of Biomarkers for

Molecularly Targeted Therapies examined the challenges limiting the broader adoption of biomarker tests for molecularly targeted therapies into clinical practice and made several recommendations.<sup>6</sup>

It determined that the field is innovating so quickly that issues as basic as common standards for evidence of clinical utility have become a barrier not just for patient access but also for test development, clinical practice and reimbursement. The committee recommended an integrated rapid learning system to improve the effective development, regulatory approval, utilization and reimbursement of biomarker tests.



## Conclusion

Biomarker testing is clearly the future of personalized cancer treatment. Research will continue identifying more markers and treatments, which will lead to improved treatments and quality of care for cancer patients, as long as they have access to testing.

Therefore, policymakers should prioritize affordable access to biomarker testing and the identified corresponding treatments. This is easier said than done, however, because of the rapid pace of innovation in the biomarker testing field.

All stakeholders should be involved in standardizing the development and validation of these tests as well as the uptake of real-world data in an integrated rapid learning system. That includes patients, providers, institutions, state and federal regulators, professional organizations and insurers. Coverage should become standard and streamlined among insurance providers.

Once the appropriate frameworks for standards are in place, policymakers can focus on campaigns for outreach and education aimed at both clinical oncologists and community-based physicians, as well as their patients.

With heightened awareness and ready access, biomarker testing can continue to equip oncology clinicians to make the more precise, individualized treatment decisions for their patients.



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