

INCREASE ACCESS TO PRECISION MEDICINE FOR PATIENTS WITH CANCER Through Biomarker Testing

The economic and human costs of cancer are significant. The National Cancer Institute estimates that in 2018, the national costs for cancer treatment were approximately \$150.8 billion;¹ in 2020, more than 1.8 million people in the United States were diagnosed with new cases of cancer² and there were over 600,000 cancer-related deaths in the United States.³ At the same time, the overall cancer mortality rate has declined over the last two decades, which may be due to the availability of better treatments.⁴ With continued investment in cancer research and the development of new treatments, the future of cancer care is promising.

For example, research and investment has led to an increase in the use of biomarkers in cancer screening, diagnosis, and treatment. For several cancer types, oncologists can now use biomarkers to personalize treatment that targets the specific characteristics of a patient's cancer, in a shift away from a one-size-fits-all approach to cancer care. Yet, many payers refuse to cover biomarker testing or impose burdensome prior authorization requirements before authorizing coverage. For patients, these barriers can result in costly delays and diminished access to effective treatments.

WHAT ARE BIOMARKERS?

In general, biomarkers are characteristics of the body that can be objectively measured.⁵ The National Cancer Institute defines a biomarker as “a biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease. A biomarker may be used to see how well the body responds to a treatment for a disease or condition.”⁶



HOW IS BIOMARKER TESTING USED IN CANCER TREATMENTS?

Biomarker testing can be used to identify genes, proteins, or other substances that provide information about a person’s cancer.⁷ Health care providers can use this information to help screen for and diagnose cancer, and also select and monitor appropriate treatments.⁸ For example, health care professionals can use this information to predict how a patient may react to a specific treatment and its potential success rate, which helps providers develop more personalized treatment plans for patients.⁹

There are two main types of “tumor markers” that can provide data about a type of cancer—tissue markers and circulating markers.¹⁰ Tissue markers can be tested after taking a small biopsy of the tumor itself, while circulating markers are found in samples of blood or other bodily fluids (also referred to as “liquid biopsies”).¹¹

According to the National Cancer Institute, liquid biopsies are not yet routinely used or covered, but they have several advantages over standard biopsies.¹² Because they do not involve surgery, liquid biopsies can be performed when surgical biopsies cannot, such as when tumors are difficult to access or when an invasive surgery would be detrimental to the patient’s health.¹³ Additionally, liquid biopsies can detect multiple cancer-associated biomarkers in a single test.¹⁴ For example, there is a biomarker test approved for the detection of genetic mutations in 324 genes and two genomic signatures in any solid tumor type. The test can also identify which patients with non-small cell lung cancer, melanoma, breast cancer, colorectal cancer, or ovarian cancer may benefit from 15 different FDA-approved targeted treatment options.¹⁵





DOES INSURANCE COVER BIOMARKER TESTING?

As summarized below, biomarker testing is not uniformly covered by public and private health plans.¹⁶ While some plans cover biomarker testing for a limited number of cancers, others impose prior authorization requirements before testing will be covered. Prior authorization policies require a health care provider or plan enrollee or beneficiary to obtain approval from their health plan before the plan will agree to cover the cost of the testing. Prior authorization can be burdensome and time consuming. Resulting delays in care can be particularly harmful to patients whose cancers can rapidly progress without prompt treatment.

Medicare

The Centers for Medicare and Medicaid Services published a National Coverage Determination (NCD) in 2020 explaining that Medicare will cover Next Generation Sequencing (i.e., a type of diagnostic biomarker testing) as a reasonable and necessary diagnostic laboratory test for patients with certain acquired or inherited cancers, so long as certain conditions are met.¹⁷ For example, for acquired cancers, the patient must have “either recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer,” among other things, while the inherited cancer category applies to only ovarian and breast cancer.¹⁸ In other words, Medicare will cover biomarker testing under a nation-wide coverage policy only under limited circumstances. However, the NCD states that Medicare Administrative Contractors (MACs)—organizations contracted by Medicare to determine coverage of items and services within smaller geographical regions—may cover Next Generation Sequencing under conditions sets forth in a MAC’s local coverage determination, which can be more permissive than the NCD.¹⁹ For example, the MAC may cover Next Generation Sequencing in the inherited cancers category for any type of cancer diagnosis if certain other conditions are met.

Medicaid

Medicaid is administered by the states pursuant to federal requirements.²⁰ Because Medicaid programs vary from state-to-state, states do not uniformly cover biomarker testing. Some state programs may cover biomarker testing for certain cancers even if the program does not expressly include such testing in their coverage policies. For example, a 2020 report on Medicaid coverage for lung cancer treatment found that the majority of Medicaid programs were silent on coverage of biomarker testing for lung cancer; yet, based on an examination of paid claims, around 40 percent of states did provide coverage for such testing.²¹

Failure by state Medicaid programs to provide coverage for biomarker testing can perpetuate health disparities among cancer patients, as studies have shown that individuals with lower socio-economic status are less likely to receive biomarker testing for cancer compared to those with higher socio-economic status.²²

Private Payers

Private payer coverage of biomarker testing varies. Many private payers are willing to cover solid tumor biomarker testing as a standard of care while coverage of liquid biomarkers is less common.²³

Payers will generally only cover testing with adequate clinical utility as supported by published, peer-reviewed evidence, or FDA-approval. For instance, a 2020 review of payer coverage policies for tumor biomarker testing found that commercial payers often will not cover tests that look for many cancer indications (e.g., a test panel with 50 genes) because not all of the biomarkers on the panel have clinical utility.²⁴ As a result, some payers will deem the entire test as experimental or investigational and use that as a basis to deny coverage.²⁵

In addition to limiting coverage to specific tests, private payers may also impose prior authorization requirements. For example, one report found that while some California regulations required coverage of cancer screenings, this requirement did not extend to biomarker testing; therefore, private payers could impose prior authorization requirements on biomarker testing. Thus, California legislators had to pass separate legislation to specifically prohibit private payers from requiring prior authorization for biomarker testing.²⁶ Imposing prior authorization on biomarker testing for cancer patients can result in unnecessary delays in access to care, disease progression, and even possibly death.

Similarly, some private payers have also required biomarker testing as a prerequisite for patients to receive access to medications used to treat specific cancers. Yet, these same payers have also refused to cover the cost of the required biomarker testing. This dangerous policy forces patients to either forgo the test and go without a life-saving medication, or pay out-of-pocket for the test.



BIOMARKER TESTING COVERAGE NEEDS TO BE REFORMED TO ENSURE PATIENTS WITH CANCER CAN ACCESS THE TREATMENTS THAT ARE BEST FOR THEM.

Determining the best course of treatment should be a decision between a patient and their health care provider. Providers should have access to an array of tools like biomarker testing that inform clinical decision making and help them develop personalized, effective treatment plans. Therefore, states should pass legislation that expands access to biomarker testing by (1) limiting burdensome prior authorization policies, and (2) requiring payers to cover the cost of biomarker testing when the plan makes it a prerequisite to receive a medication. For example, in 2021, [California](#)²⁷ passed legislation prohibiting the use of prior authorization on biomarker testing.²⁸ Similarly, [Illinois](#) and [Louisiana](#) have also passed legislation that²⁹ expanded access and coverage of biomarker testing. Aimed Alliance encourages states to adopt similar legislation to ensure providers have access to detailed information that can inform patient treatment planning, and protect patients with cancer from harmful policies that delays access to treatment.



HOW CAN YOU HELP?

Call your state legislators and ask them to introduce or pass state legislation that ensures access to biomarker testing and limits burdensome prior authorization requirements for biomarker testing.

WHERE CAN YOU GET MORE INFORMATION?

For more information, contact:

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