An estimated 1.9 million people who received a cancer diagnosis in 2023 now face a daunting journey as they navigate the medical, psychosocial, and economic effects of malignancy, which impact patients long after treatment is complete. Tremendous gains have been made in cancer prevention, detection, and treatment; all too often, however, patients cannot access these advanced diagnostics and treatments. One persistent obstacle has been a lack of consistent, affordable access to biomarker testing. The Association of Cancer Care Centers (ACCC) offers this review of current efforts to expand access to biomarker testing at the state-regulated level—including coverage for Medicaid beneficiaries—and highlights resources developed to aid its implementation.

**WHAT ARE BIOMARKERS?**

Biomarkers, which are also referred to as tumor or molecular markers, are biological changes that reflect the body’s response to cancer. These changes can inform clinicians about a cancer (eg, how aggressive it is, what kind of treatment might be effective, and whether a treatment is working). Biomarkers can be found in body tissues or fluids (eg, blood, urine, and stool) and from the tumors or their fragments. Such biomarkers are generally either circulating markers or tumor tissue (or cell) markers. Tumor biomarkers are usually found in liquid or solid tumor biopsies samples; they may be used for diagnosis of disease and selection of a therapy that targets a specific genetic mutation. Examples of these biomarkers include estrogen and progesterone receptors in breast cancer, FGFR3 in bladder cancer, and PD-L1 when determining the usefulness of immune checkpoint inhibition.

**COVERAGE OF BIOMARKER TESTING AND IMPROVING HEALTH EQUITY**

Fortunately, Medicare has implemented biomarker testing policies to cover the costs of various tests through both national and local coverage determinations.

However, for individuals younger than 64 years who have health insurance coverage through a state-regulated or Medicaid plan (approximately 15% of patients with cancer), coverage can be limited and inconsistent. Results of a study conducted by the National Comprehensive Cancer Network (NCCN) showed that Medicaid recipients were less likely to have biomarker testing or receive first-line biomarker-guided therapies than people with other types of healthcare coverage. When Medicaid patients did receive initial biomarker testing, it was often not comprehensive, or it resulted in a lengthy, overly-examined insurance review process. According to the American Cancer Society Cancer Action Network (ACS CAN), individuals who underwent broad, panel-based biomarker testing faced an initial increased cost (average $1200) compared with those who opted for limited, panel-based testing. Nonetheless, recipients of broad, panel-based biomarker testing realized an average monthly reduction of approximately $8500 in total care expenses that resulted in significant long-term savings.

Another study conducted by ACCC and the LUNGevity Foundation investigated barriers to equitable biomarker testing in patients with non–small cell lung cancer. Although oncology providers were likely to discuss and order guideline-concordant testing, patients with perceived lower socioeconomic status and low health literacy underwent less testing. Legislative efforts currently underway in multiple states are crucial to breaking down barriers to essential testing for Medicaid beneficiaries and access to the most up-to-date treatments or clinical trial enrollment.

According to ACS CAN, 15 states have enacted laws requiring state-regulated plans to cover biomarker testing for the diagnosis, treatment, management, and ongoing monitoring of a disease or condition (Figure 1).
However, the required tests must fall into one of the following categories:

- Labeled indications for a test approved or cleared by the Food and Drug Administration (FDA)
- Indications for an FDA-approved drug
- Warnings and precautions mentioned in FDA-approved drug labels
- Centers for Medicare & Medicaid Services (CMS) national coverage determinations or Medicare Administrative Contractor (MAC) local coverage determinations
- Adherence with nationally recognized clinical practice guidelines and consensus statements.¹⁰

This enables clinicians to make informed choices, select appropriate tests for each patient, and ensure that medical decisions are not disrupted.

LEGISLATION TO EXPAND ACCESS TO BIOMARKER TESTING

![Map of Legislative Efforts](image-source)

**Figure 1. Map of Legislative Efforts as of April 2024**

*Image Source: [fightcancer.org/what-we-do/access-biomarker-testing](http://fightcancer.org/what-we-do/access-biomarker-testing)*

**Legislation enacted:** AZ, AR*, CA, GA, IL, IN, KY, LA*, MD, MN, NM, NY, OK, RI, TX

**Legislation introduced:** CO, FL**, IA, MA, ME, NV, OH, PA, VT, WA, WV

* Private plans only  ** Awaiting signature, public plans only

INITIATING MEASURES FOR IMPLEMENTATION

Jordan Karwedsky, a financial counselor at Green Bay Oncology, underscored the experience from the patient’s perspective when she said,

“The wait is anxiety inducing, and patients worry that if it isn’t covered by insurance, they question if the test is something they should have done. No patient should ever have to think about this.”

In the 15 states where legislation has been enacted to include biomarker testing coverage, there is a critical need for continued efforts beyond the passage of legislation. Comprehensive implementation strategies that require collaboration and proactive engagement from both healthcare providers and payers are essential in the next phase. This need underscores the significance of the groundwork laid by leaders of provider and patient organizations who have been diligently involved in creating educational initiatives, lexicon development, guidelines, and quality measures that are invaluable in the progression of equitable biomarker testing access.¹⁰
Recognizing this landscape’s complexity, ACCC has curated essential resources across various platforms to support multidisciplinary teams working toward expanding access to biomarker testing for newly covered patients. These resources include:

- A comprehensive directory of common biomarker lexicon
- A robust resource library featuring materials relevant to cancer biomarkers and the intricacies of biomarker testing
- In-depth, how-to webinars (eg, covering preanalytics and tissue stewardship, biomarker testing costs and coverage, genetic vs genomic testing, and integration of comprehensive testing results) on guiding cancer programs that use tools to effectively implement biomarker testing protocols
- Specialized biomarker testing pathways and quality improvement resources tailored to various cancer types, including non-small cell lung cancer and colorectal cancer.²

Many questions remain, leaving patients and practices in flux as payers navigate the integration of legislative changes into their plans. However, these multidisciplinary teams have a crucial opportunity to initiate groundwork now and thereby lay the foundation for a seamless transition. This includes activities such as:

- Identifying patients who may now be covered and proactively assessing future patients who may qualify for coverage
- Conducting outreach initiatives to engage with insurance providers and gain insights into their implementation plans as they develop
- Researching the denial and appeal processes to ensure quicker resolutions for patients facing potential hurdles.

Through collaboration and strategic partnerships, ACCC is committed to developing further resources to aid cancer programs in their mission to guarantee equitable access to biomarker testing for patients across diverse healthcare settings.

> “Financial distress can impact treatment outcomes and quality of life. [The expense of] biomarker testing is just one of the many, many bills patients get during their cancer journey.”

— Aimee Hoch, LSW, OSW-C, Oncology Financial Navigator, Grand View Health Cancer Center

> “The biggest challenges [to providing access to testing for Medicaid patients] are primarily the payer and the timeline. [Biomarker testing is] not as simple as picking a test and ordering it. You have to think about the finances behind it, and most tests have to get authorized.”

— Kathy W. Oubre, MS; Chief Executive Officer; Pontchartrain Cancer Center

Listen now: Biomarker Testing for Medicaid Beneficiaries – [Mini Podcast]
REFERENCES


