

# Biomarker Testing: Increasing Access to Precision Medicine in Pennsylvania

**Precision medicine uses information about a person's own genes or proteins to inform diagnosis, prognosis, therapy selection, and to monitor how well therapy is working.**

The knowledge and practice of precision medicine in cancer have been progressing rapidly and advances have led to targeted cancer therapies, which work by interfering with specific cellular processes involved in the growth, spread, and progression of cancer.

## **Biomarker testing can help determine the best treatment for a patient.**

Treatment with targeted therapy often requires diagnostic testing known as **biomarker testing**, to analyze biological samples (e.g., blood, tumor tissue) taken from a patient to identify and evaluate specific biomarkers. Research shows that targeted therapy can improve patient survival and quality of life. When doctors connect patients to the most effective treatment for their cancer, patients can avoid treatments that will be ineffective or have more adverse side effects.

Biomarker testing, in addition to *matching patients with the most effective treatment for their disease*, can also be used to:

- Identify the likeliness of disease recurrence or progression
- Predict a drug's efficacy or likelihood of toxicity
- Identify signs of disease recurrence before it is visible on imaging

While most current applications are in cancer, biomarker testing is becoming increasingly important to the treatment of other diseases including arthritis, other autoimmune conditions, and rare diseases. There is research happening in many other areas including Alzheimer's, Parkinson's and other neurological conditions, cardiology and more.

## **Barriers to Biomarker Testing and Precision Medicine**

Insurance coverage for biomarker testing is failing to keep pace with innovations and advancements in treatment. A 2022 analysis found that 71% of insurance policies are *more restrictive* than the National Comprehensive Cancer Network (NCCN) guidelines for biomarker testing of advanced breast, lung, melanoma, and prostate cancers.<sup>i</sup> Nearly 9 in 10 providers rely on NCCN guidelines in determining when to recommend biomarker testing.<sup>ii</sup> We must work to dismantle barriers that prevent *all* patients from benefiting from biomarker testing and precision medicine.

## **Legislative Action to Expand Coverage of Biomarker Testing**

In order for more patients to have access to the biomarker testing they need; ACS CAN supports expanding appropriate coverage of biomarker testing for public and private insurance plans. We support SB 954,

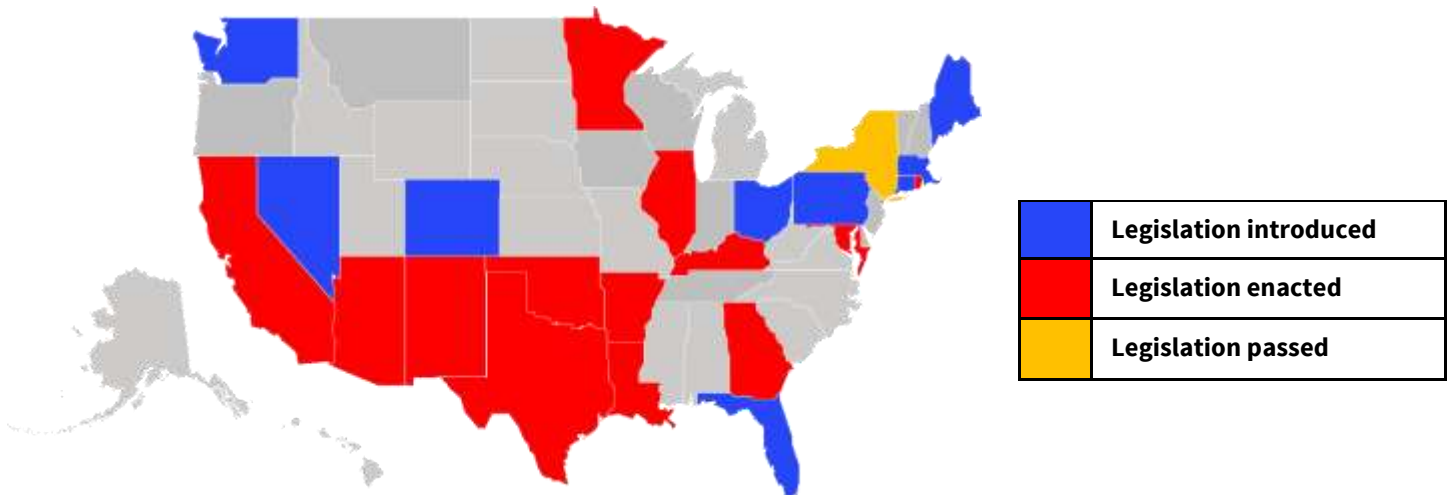
introduced by Senators Devlin Robinson and Lisa Boscola and HB 1754, introduced by Representatives Kyle Mullins and Bryan Cutler.

Without action to expand coverage and access to biomarker testing, advances in precision medicine could increase existing disparities in cancer outcomes by race, ethnicity, income, and geography.

SB 954 and HB 1754 **would** require state regulated insurance plans to cover biomarker testing for the purposes of “diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee’s disease or condition” when supported by scientific and medical evidence including:

1. Labeled indications for an FDA-approved or -cleared test;
2. Indicated tests for an FDA-approved drug;
3. Warnings and precautions on FDA-approved drug labels;
4. Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations or Medicare Administrative Contractor (MAC) Local Coverage Determinations; or
5. Nationally recognized clinical practice guidelines and consensus statements.

The legislation **would not** require coverage for the purposes of screening, or genetic testing to determine if someone is at risk for later developing cancer or another disease.



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

Legislation passed (2023 session): NY

Legislation introduced/expected in 2023: CO, CT, FL, MA, ME, NV, OH, PA, WA

\*Commercial coverage only

<sup>i</sup> Wong WB, Anina D, Lin CW, and Adams D. Alignment of health plan coverage policies for somatic multigene panel testing with clinical guidelines in select solid tumors. Per Med 2022; 10.2217/pme-2021-0174.

<sup>ii</sup> ACS CAN. “Survey Findings Summary: Understanding Provider Utilization of Cancer Biomarker Testing Across Cancers.” December 2021. [https://www.fightcancer.org/sites/default/files/national\\_documents/provider\\_utilization\\_of\\_biomarker\\_testing\\_polling\\_memo\\_dec\\_2021.pdf](https://www.fightcancer.org/sites/default/files/national_documents/provider_utilization_of_biomarker_testing_polling_memo_dec_2021.pdf)