Biomarker Testing FAQs

What does this legislation do? What evidence is required to justify coverage?

This legislation establishes clear guardrails to align coverage of biomarker testing with robust and reputable sources of evidence. Tests will not meet the criteria spelled out without having clear benefit, and physicians will not order tests that won't provide useful information. Insurers are already covering much of this testing – this is about making sure plans play by the same rules and keep up with the science so that patients get the testing they need to get the right treatment at the right time.

Nothing in the legislation requires all biomarker tests to be covered. Insurance plans would be required to cover biomarker tests only when they meet clear and robust medical and scientific evidence standards as defined in the bill, and only for the purposes spelled out in the bill. These sources of evidence are included to ensure that tests are covered if and only if they are demonstrated to be beneficial to patients.

Does every cancer patient need biomarker testing?

No, biomarker testing is not currently indicated for all cancer patients. This legislation requires coverage for testing in line with medical and scientific evidence, like the clinical practice guidelines that oncologists rely on to determine when biomarker testing is appropriate.

What disparities exist in biomarker testing? How does this legislation help advance health equity?

Improving access to biomarker testing is key for reducing disparities in cancer outcomes. The research shows that people of color – and particularly Black people - are not benefitting from biomarker testing at the same rates that whites are. Biomarker-driven therapies can help extend and save lives from some of the diseases that hit Black families hardest – metastatic lung, prostate, and breast cancers.

These personalized treatments are the future of health care – not just for cancer, but for other conditions as well. Let's make sure everyone can benefit.

What's the difference between genetic testing for inherited risk and biomarker testing?

Biomarker testing analyzes samples of tissue, blood or other biospecimen to identify somatic (acquired) or germline (inherited) mutations that impact treatment decisions. Biomarker testing is used in people who have already been diagnosed with cancer (or another condition). This is separate from genetic testing for inherited risk which looks for inherited mutations to identify individuals who may be at a higher risk for later developing cancer or current cancer patients whose family members may want to get genetic testing and counseling.

Genetic testing to determine risk for later developing cancer would not be covered under "diagnosis, treatment, appropriate management, or ongoing monitoring" and is not required to be covered by this legislation.

Will this increase insurance costs?

Biomarker testing (and precision medicine) can not only save lives and improve quality of life – but this type of testing can potentially reduce health care costs by identifying which treatments can be most effective for which individual

patient.

By avoiding treatments that will be ineffective or cause adverse side effects, patients can avoid unnecessary suffering and expedite cures.

A recent study by Milliman looking at the cost implications of similar legislation estimates that robust coverage of biomarker testing would result in premium impact of $0.14-$0.51 per member per month in the private market. This does not account for any potential cost savings from avoiding ineffective or unnecessary treatments. It does include additional profit insurers would build into the benefit costs. The average cost to insurers per biomarker test in the private market was $224.

What states have passed similar legislation?

Arizona, Illinois, Louisiana, and Rhode Island have passed bills requiring insurance plans to cover biomarker testing in line with medical and scientific evidence. Similar legislation is under current consideration in many other states.

Does the bill mandate providers to order biomarker tests or dictate treatment decisions?

No. This legislation would require insurance plans cover biomarker testing if it is ordered by a treating provider for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition when supported by the medical and scientific evidence defined in the bill. It is still up to a treating provider to determine what tests to recommend or order for an individual patient. Nothing in this legislation would require any individual patient to receive any testing or treatment they do not want.

Can the information obtained through biomarker testing be used to discriminate against the patient in health coverage, life insurance coverage, etc.?

When someone gets biomarker testing (as defined in this legislation) they already have cancer, and the testing is used to determine which treatment is appropriate and/or how aggressive their cancer may be.

In 2008, the Genetic Information Nondiscrimination Act (GINA), a bill supported by ACS CAN, was passed, barring discrimination in health insurance and employment based on genetic information.

Does this require insurers to pay for tests like Ancestry or 23andMe?

No. Direct to consumer genetic tests would not meet the criteria for "diagnosis, treatment, appropriate management and ongoing monitoring of a disease or condition."

What are some examples of "nationally recognized clinical practice guidelines"?

The National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO), College of American Pathologists (CAP), International Association for the Study of Lung Cancer (IASLC), Association of Molecular Pathologists (AMP), Children's Oncology Group (COG), and Clinical Pharmacogenetics Implementation Consortium (CPIC) are all entities that fit the definition of nationally recognized clinical practice guidelines and issue guidelines on biomarker testing.

Tying coverage to national guidelines and recommendations in statute enables the legislation to keep up with the science. As the guidelines are updated, the statute will remain relevant in perpetuity, instead of requiring revisions for every update. The science is evolving rapidly – and we want to make sure patients can benefit as soon as new breakthroughs are made.

Are other words used to describe biomarker testing?

Mutation testing, genomic testing, molecular testing and molecular profiling, tumor profiling are all other terms for biomarker testing. ACS CAN uses biomarker testing.
Biomarker testing is sometimes subdivided into diagnostic biomarkers, prognostic biomarkers, pharmacogenomic biomarkers, predictive biomarkers, and monitoring biomarkers. This legislation covers all these types of biomarker testing when supported by medical evidence, like clinical treatment guidelines.

Diagnostic biomarkers are used to confirm the presence of a disease or condition, or to identify individuals with a subtype of the disease. This is one of the earliest uses of biomarker testing in cancer.

Prognostic biomarkers are used to identify the likelihood of disease recurrence or progression in patients after diagnosis.

Pharmacogenomic (PGx) biomarkers are used to predict a drug's efficacy or likelihood of toxicity. The same treatment given to patients with the same disease can produce different responses based on each person's inherited genes.

Predictive biomarkers are used to help doctors to identify the most effective treatment for a patient. These biomarkers help to identify individuals who are more likely than those without the biomarker to experience a favorable (or unfavorable) response to a treatment or therapy.

Monitoring biomarkers are used to detect signs of disease progression or recurrence and may catch changes before they are visible through traditional monitoring, like scans.

The results of biomarker testing are key to precision oncology – which can include: targeted therapy, hormone therapy, immunotherapy and stem cell or cell-based therapy.

Why limit this legislation to small employer/individual insurance plans and Medicaid?

Large employer plans are regulated at the federal level and not subject to state regulations.

Do plans in my state already cover biomarker testing?

Most plans cover some biomarker testing for some patients. Generally speaking, large employer sponsored plans and Medicare tend to have better coverage of biomarker testing than smaller private plans and Medicaid.

A journal article comparing each state's largest insurance coverage policies to the National Comprehensive Cancer Network (NCCN) biomarker testing guidelines found that most plans are more restrictive than NCCN's testing guidelines for multigene panel tests. This paper demonstrates that plans are not following the science and many patients who should be getting biomarker testing are likely unable to. Nationally, 71% of policies reviewed were "more restrictive" than NCCN guidelines for biomarker testing for breast, non-small cell lung cancer, melanoma and/or prostate cancer.[1]

[1] 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.