Biotechnology Innovation Organization
1201 New York Ave NW
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June 12, 2024

Chair Lampton and Members of the
House Insurance Committee
Ohio House of Representatives
Room 122
Columbus, OH 43215

RE: Testimony in Support of HB 24: Require health plan and Medicaid coverage of biomarker testing

Chair Lampton and Members of the Committee:

The Biotechnology Innovation Organization (BIO) thanks the committee for the opportunity to comment in support of HB 24, proposed legislation to require coverage for biomarker testing.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. Our members are committed to advancing science and improving the health and well-being of our planet using biotechnology.

Position: BIO supports timely, appropriate, and equitable access to biomarker testing as well as adequate coverage and reimbursement by public and private payers when testing is supported by clinical guidelines or peer-reviewed scientific evidence. Delays in biomarker testing and coverage may lead to worse outcomes for patients.

Continuing advances in science and genomics are driving an increased understanding of human physiology and how diseases affect the body; these advances are helping researchers identify new biomarkers. As more biomarkers are identified, they have the potential to greatly enhance the drug development process by providing researchers with new ways to measure disease activity, reduce the amount of time required to show a medicine is safe or effective, and enable the development of more personalized, precision medicine— particularly where multiple biomarkers can inform the use of targeted drug combinations. Biomarkers can also allow researchers to better understand how effective a treatment is against a disease with endpoints that are difficult to define, providing clinicians with additional informative measurements in the early diagnosis of a disease and identifying differences in responses between individuals or subpopulations.

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The development of personalized medicines that are more tailored to the individual patient using biomarkers helps drive efficiencies and improvements in patient care. That is because biomarkers can help identify those most likely to benefit from a specific treatment. For example, biomarkers are often used in cancer treatments to identify patients with tumors expressing certain genomic characteristics that indicate those patients are likely to respond to a targeted cancer therapy. In another example, they can be used to ensure that a certain patient with a rare disease will most likely benefit from a specific therapy, such as a gene therapy.

Access to biomarker testing should not be delayed, as this may have detrimental effects on patient outcomes. If patients do not have access to biomarker testing, they may not be offered life-saving targeted therapies that can improve their overall health outcome. Additionally, it is important that if access to a particular therapy is dependent upon a specific biomarker, coverage policies must reflect the new advances in treatment. Coverage policies should never stand in the way of access to treatment.

Biomarker testing for the purposes of diagnosis, treatment and ongoing patient monitoring is not done through at home genetic DNA testing. It is done in clinical laboratory by healthcare professionals working within the scope of their license and experience to identify the presence of one or more biomarkers in a patient's sample. A patient's health care provider must always have the ability to order all comprehensive biomarker testing panels necessary to ensure appropriate treatment and continuing care.

Disparities in access to biomarker testing exist across the United States. Coverage expansion and accessibility to biomarker testing can mitigate disparities in health outcomes by race, ethnicity, income, and geography. A recent research report concluded there are geographic variations in the number of commercial lives within each state under a more restrictive multigene panel test (MGPT) coverage policy.[1] More specifically, the report found that a total of 34 states had 50% or more fully insured commercial lives covered by a plan classified as more restrictive than the clinical guidelines.[2]

BIO supports the continual assessment of coverage requirements by public and private payers to ensure coverage keeps pace with scientific innovation and advances in clinical care. Public, and private payers should regularly review clinical guidelines, existing medical compendia, CMS

[1] *Alignment of health plan coverage policies for somatic multigene panel testing with clinical guidelines in select solid tumors* - William B Wong, Daniele Anina, Chia-Wei Lin, and Devon V Adams
Personalized Medicine 2022 19:3, 171-180
[2] Ibid.

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coverage guidelines, recommendations of health professional organizations, and consensus statements to update their testing policies.

Biomarker testing should not be subject to lifetime limits. As disease stages progress over time and can vary from patient to patient, biomarker testing should be covered for all relevant panels of tests at any time in the continuum of care, if determined necessary by a health care professional.

For these reasons, BIO and its members urge the passage of HB 24, coverage for biomarker testing.

Thank you for your consideration.

/S/

Lilly Melander
Director, State Government Affairs – Midwestern Region
The Biotechnology Innovation Organization (BIO)