



May 7th, 2024

The Honorable Brian E. Lampton, Chairman
Insurance Committee
Ohio House of Representatives
77 South High Street, Floor 13
Columbus, OH 43215

RE: HB 24 (White) – Support

Dear Chairman Lampton:

On behalf of Guardant Health, the market leader in liquid biopsy for advanced cancer patients, I am writing to encourage you to support HB 24. Sponsored by State Representative Andrea White and the American Cancer Society Cancer Action Network (ACS CAN), this bill would dramatically improve Ohio patients' access to biomarker testing, which is an integral part of precision medicine in cancer care.

Guardant Health is a global precision oncology company with over 1800 employees and our biomarker test, Guardant360® CDx, was the first FDA-approved liquid biopsy for comprehensive genomic profiling (CGP) in advanced cancer patients across all solid cancers, and for use as a companion diagnostic to identify non-small cell lung cancer (NSCLC) patients with EGFR mutations who may benefit from Tagrisso® (osimertinib). Guardant360® CDx has since obtained three more FDA approvals for use as a companion diagnostic for lung cancer patients and an additional indication in breast cancer. To date, Guardant360 has been clinically validated with more than 425 publications; trusted by more than 15,000 oncologists with over 300,000 patients tested; and is broadly covered by Medicare and many private payers, representing 300 million+ lives.

Cutting edge cancer treatment increasingly involves the use of targeted therapies, which necessitates up-front biomarker testing to precisely match a patient with the most appropriate therapy for their cancer. Patients' lives are changed every day by having access to biomarker testing to unlock this essential information. For example, over 30% of NSCLC patients have targetable variants and are candidates for tailored therapy that can increase overall survival by years.¹ Compared to patients receiving standard chemotherapy, cancer patients who receive biomarker testing and targeted therapy have a significant increase in median overall survival and lower average treatment costs.²

Yet despite significant evidence pointing to the benefits, testing rates continue to lag behind clinical guideline recommendations. While this is a multi-faceted problem, insufficient insurance coverage for biomarker testing remains a major barrier to access for late-stage cancer patients

While both commercial plans and Medicaid currently cover some biomarker tests, they do not always cover the *right* biomarker test for a patient's need. Clinical guidelines, such as those of the National Comprehensive Cancer Network (NCCN), are increasingly recognizing that CGP can provide doctors and patients with the clearest picture of how to treat an individual's cancer. Guidelines are constantly being updated with new biomarkers and multiple versions of NCCN guidelines are published each year to account for this fact. As these biomarkers become actionable and are added to guidelines, patients who have had comprehensive testing are able to benefit directly from these advances in treatment.

By contrast, some health plans only cover smaller gene panels that may leave out needed or emerging biomarkers. As medicine advances rapidly, the incomplete information could necessitate multiple expensive

¹ Tan, A.C. & Tan, D.S.W. (2022). Targeted Therapies for Lung Cancer Patients with Oncogenic Driver Molecular Alterations. *Journal of Clinical Oncology* 40(6) 611-625. DOI: 10.1200/JCO.21.01626

² Haslem DS, Chakravarty I, Fulde G, et al. Precision oncology in advanced cancer patients improves overall survival with lower weekly healthcare costs. *Oncotarget*. 2018;9(15):12316-12322.



biopsies, cause delays in treatment, and limit opportunities for clinical trial participation. While many health plans are now beginning to cover comprehensive testing in NSCLC, there are many patients with other cancers (e.g., colorectal cancer (CRC), breast, and prostate) who also have a potential targeted therapy available but simply do not have access to comprehensive testing even though it is supported in guidelines. For example, Guardant360 is broadly covered by Medicare across all solid tumor cancers, but for over 1 million of the privately insured patients in Ohio, testing is not covered outside of lung and occasionally breast cancer. This means that these patients would not have access to the most current guideline-recommended testing if they were to receive a different cancer diagnosis.

Historically, differences in the cost associated with the CPT codes used for payment of smaller versus larger panels have led plans to limit access to CGP. Plans often refer to this testing as “investigational” or “experimental” even though it is supported by guidelines and hundreds of peer-reviewed publications. HB 24 would change this and ensure that comprehensive biomarker testing is covered where supported by clear and rigorous scientific evidence, including FDA labeling, Medicare National and Local Coverage Determinations, and well vetted clinical practice guidelines. Essentially, HB 24 puts the decision of selecting the appropriate test in the hands of practicing physicians rather than insurance companies.

This is especially important from a health equity perspective. Many doctors, particularly community oncologists, can be hesitant to order comprehensive testing for these patients because there is currently so much confusion around coverage. This is born out in the data, which shows that biomarker testing varies by practice location. NCI Cancer Centers have the highest rates of ordering large panel testing and the highest rates of patients on targeted therapies, whereas this rate is significantly lower in the community setting.³ Given the uneven geographic distribution of healthcare infrastructure, underserved and rural populations are more likely to be treated by community oncologists than at academic medical centers, which tend to be concentrated in metropolitan areas.⁴ Legislation that expands and standardizes biomarker testing coverage will improve access, especially for underserved patients that already face challenges in accessing oncology care.

Health care coverage for biomarker testing is failing to keep pace with scientific advancements, but timely access to appropriate biomarker testing as proposed by HB 24 will result in better health outcomes, advance health equity, and reduced costs. For these reasons, we respectfully ask for your support.

Sincerely,

Jennifer N. Higgins
Senior Vice President, Global Public Affairs

Cc: Members, Insurance Committee

³ Roberts TJ, Kehl KL, Brooks GA, et al. (2023). Practice-Level Variation in Molecular Testing and Use of Targeted Therapy for Patients With Non-Small Cell Lung Cancer and Colorectal Cancer. *JAMA Netw Open*. 6(4):e2310809. doi:10.1001/jamanetworkopen.2023.10809

⁴ Closing the Rural Cancer Care Gap: Three Institutional Approaches

Laura A. Levit, Leslie Byatt, Alan P. Lyss, Electra D. Paskett, Kathryn Levit, Kelsey Kirkwood, Caroline Schenkel, and Richard L. Schilsky
JCO Oncology Practice 2020 16:7, 422-430