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Ohio House Health Committee 1 Capitol Square Columbus, OH 43215

Re: HB 8 - biomarker testing legislation

Dear Chair Schmidt and Members of the Ohio House Health Committee,

On behalf of all our organizations and the hundreds of thousands of patients and providers we represent across Ohio, we respectfully request that you pass House Bill 8, which will ensure Ohioans covered by state-regulated insurance plans, including Medicaid, have coverage for biomarker testing when medically appropriate.

Thank you for scheduling a second hearing on HB 8. On June 26, 2024, the Ohio House of Representatives passed HB 24, the biomarker bill from the 135th General Assembly. House Bill 8 is the "as passed by House" version of HB 24. To date, 20 states have passed legislation to expand coverage of biomarker testing. On behalf of the patients and health care providers we represent across Ohio, we ask that the committee swiftly address this important matter and pass HB 8.

Timely access to guideline-indicated comprehensive biomarker testing will enable more patients to access the most effective treatments for their disease. Progress in improving health outcomes increasingly involves the use of precision medicine, which uses information about a person's own genes or proteins to diagnose and treat diseases. Access to precision medicine often requires biomarker testing, which analyzes biological samples to identify biomarkers (genetic mutations, molecular signatures) that may impact treatment decisions.

Biomarker testing is increasingly important for cancer care – and for the treatment of other diseases. Thirty-seven of the 62 oncology drugs launched in the past five years require or recommend biomarker testing prior to use. Biomarker testing is increasingly important to enrolling patients in clinical trials as the number and percentage of cancer clinical trials that involve biomarkers has grown significantly.

Unfortunately, there is currently limited and disparate access to biomarker testing. A significant percentage of cancer patients and survivors do not receive biomarker testing because it is not covered by their insurer or the out-of-pocket costs would be too high. A recent study found that 78% of Ohioans are covered by plans that have more restrictive coverage than what is recommended by the National Comprehensive Cancer Network® (NCCN) guidelines for several common cancers.

Access to biomarker testing can help achieve the triple aim of health care including better health outcomes, improved quality of life, and reduced costs. This testing can lead to treatments with fewer side effects, longer survival, and allow patients to avoid treatments that are likely to be ineffective or unnecessary. Exposure to these ineffective treatments can exacerbate the physical, emotional, and economic burdens of disease.

Studies have found upfront broader biomarker testing results in substantial cost savings for commercial payers^{vi} and decreased expected testing procedure costs to the health plan.^{vii} Some studies have found minimal cost increases as a result of the costs of more effective treatment and prolonged patient survival.^{viii} The purpose of this legislation is to enable more Ohioans to access appropriate testing; currently the cost of biomarker testing – when not covered by insurance – is a significant barrier for many patients. There is a wide range of costs for biomarker tests, depending on the size and complexity of the appropriate test for a particular patient. Although the average cost to an insurer per biomarker test is just \$224^{ix}, the out-of-pocket cost to a patient when insurance does not cover the needed test can exceed \$10,000 for some tests.

Thank you for scheduling a second hearing on HB 8. We respectfully ask that you schedule another hearing and move HB 8 through the committee process as soon as possible. Please reach out to Leo Almeida, ACS CAN Government Relations Director for Ohio at Leo.Almeida@cancer.org with any questions.

Sincerely,

The Academy of Medicine of Cleveland & Northern Ohio

AdvaMed Aimed Alliance ALS Association

Alzheimer's Association

American Association of Clinical Urologists, Inc. American Cancer Society Cancer Action Network

American Lung Association American Kidney Fund

American Urological Association

Arthritis Foundation

Association for Clinical Oncology

CancerCare

Cancer Support Community/Gilda's Club

Case Western Reserve University – Case Comprehensive

Cancer Center Cervivor, Inc. Cleveland Clinic CLL Society

Coalition of State Rheumatology Organizations

Colon Cancer Coalition

Color of Gastrointestinal Illnesses Colorectal Cancer Alliance Community Oncology Alliance Crohn's and Colitis Foundation

Debbie's Dream Foundation: Curing Stomach Cancer

End Preeclampsia Exon 20 Group

Fight Colorectal Cancer

Global Colon Cancer Association

Global Liver Institute

GO2 Foundation for Lung Cancer

Heal Collaborative

ICAN, International Cancer Advocacy Network

Infusion Access Foundation

International Foundation for Autoimmune & Autoinflammatory Arthritis (AiA)

KRAS Kickers

Little Hercules Foundation Lung Cancer Research Foundation

LUNGevity Foundation

Lupus and Allied Diseases Association, Inc.

Melanoma Research Foundation The Michael J. Fox Foundation National Marrow Donor Program

National Organization for Rare Disorders

National Ovarian Cancer Coalition National Psoriasis Foundation Nationwide Children's Hospital

OhioHealth

Ohio Academy of Family Physicians

Ohio Association of Community Health Centers

Ohio Association of Physician Assistants

Ohio Chapter of the American Academy of Pediatrics Ohio Chapter of the American College of Cardiology The Ohio Chapter of the American College of Surgeons

Ohio Hematology Oncology Society

Ohio Hospital Association Ohio Jewish Communities Ohio Life Sciences Ohio Nurses Association

Ohio Nurses Association – Columbus Chapter

Ohio Osteopathic Association Ohio State Medical Association

The Ohio State University Comprehensive Cancer Center – James Cancer Hospital and Solove Research Institute

Ohio Urological Society Oncology Hematology Care Oncology Nursing Society

One Cancer Place
Patients Rising
PDL1 Amplifieds
Premier Health
Sharsheret
Susan G. Komen
Tigerlilly foundation
Transplant Life Foundation

Triage Cancer

Southeastern Ohio Regional Medical Center

UC Health

University Hospitals

VHL Alliance

ZERO Prostate Cancer

¹ Biomarker Testing Can Direct Care, but Only If Clinicians Perform the Right Tests. Evidence-Based Oncology, February 2020, Volume 26, Issue 2. https://www.ajmc.com/view/biomarker-testing-can-direct-care-but-only-if-clinicians-perform-the-right-tests

ii Mikyung Kelly Seo & John Cairns. Do cancer biomarkers make targeted therapies cost-effective? A systematic review in metastatic colorectal cancer. PLOS. September 26, 2018 https://doi.org/10.1371/journal.pone.0204496

iii Global Oncology Trends 2021. IQVIA Institute; June 2021.

The Evolution of Biomarker Use in Clinical Trials for Cancer Treatment,
 https://www.personalizedmedicinecoalition.org/Userfiles/PMC-
 Corporate/file/The Evolution of Biomarker Use in Clinical Trials for Cancer Treatments.pdf

- ^v Wong WB, Anina D, Lin CW, Adams DV. 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. (https://www.ncbi.nlm.nih.gov/pubmed/35118882)
- vi Economic Impact of Next-Generation Sequencing Versus Single-Gene Testing to Detect Genomic Alterations in Metastatic Non–Small-Cell Lung Cancer Using a Decision Analytic Model

DOI: 10.1200/PO.18.00356 JCO Precision Oncology - published online May 16, 2019.

- vii Budget Impact of Next-Generation Sequencing for Molecular Assessment of Advanced Non–Small Cell Lung Cancer https://doi.org/10.1016/j.jval.2018.04.1372
- viii Budget Impact of Next-Generation Sequencing for Molecular Assessment of Advanced Non–Small Cell Lung Cancer https://doi.org/10.1016/j.jval.2018.04.1372
- ix Dieguez, G. Carioto, J. The landscape of biomarker testing coverage in the United States. Milliman. https://www.milliman.com/en/insight/the-landscape-of-biomarker-testing-coverage-in-the-US