

February 14, 2023

Dear Senator,

We are writing to urge your support for House Bill 180 AN ACT relating to coverage for biomarker testing which will allow more patients across the state to benefit from the latest advances in personalized medicine.

**Biomarker testing connects patients with the most effective treatments.**

The results of biomarker testing can help determine the treatments that will work best for a specific patient and can also allow patients to avoid treatments that are likely to be ineffective. In certain areas of medicine, like cancer care, advances in precision medicine have been progressing rapidly in recent years and have led to targeted cancer therapies that work by interfering with specific cellular processes involved in the growth, spread, and progression of cancer. In other words, effective treatments can be selected based on the tumor itself, rather than just its location in the body. Additionally, appropriate biomarker testing can help doctors determine which cancer patients are more likely to have recurring or more aggressive disease so that patients at low risk of recurrence may choose to avoid unnecessary treatment.

**Research shows that targeted therapy can improve health outcomes, increase quality of life, and prolong patient survival.<sup>1,2</sup>**

Using the traditional trial and error method to identify an effective treatment for a particular patient can take months — even years. In chronic, degenerative diseases like rheumatoid arthritis, any length of time spent trying (and failing) on ineffective treatments allows the disease to continue causing irreversible damage to the joints, increasing health care consumption and costs. In cancer care and some autoimmune conditions, the length of time it takes to identify an effective treatment can be a matter of life or death. In all cases, ineffective treatments exacerbate the physical, emotional, and economic burdens of disease, and the price is paid by both the patient and the insurer.

**Insurance coverage for medically appropriate biomarker testing is failing to keep pace with innovations and advancements in treatment.**

Despite the clear benefits of biomarker testing, many insurance plans do not cover evidence-based biomarker testing for all patients who need it.

Despite evidence pointing to the clinical benefits associated with biomarker testing, routine clinical use does not always follow, and testing rates lag behind clinical guideline recommendations. In a 2021 survey,

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<sup>1</sup> Gutierrez, M. E., Choi, K., Lanman, R. B., Licitra, E. J., Skrzypczak, S. M., Pe Benito, R., Wu, T., Arunajadai, S., Kaur, S., Harper, H., Pecora, A. L., Schultz, E. V., & Goldberg, S. L. (2017). Genomic Profiling of Advanced Non-Small Cell Lung Cancer in Community Settings: Gaps and Opportunities. *Clinical lung cancer*, 18(6), 651–659. <https://doi.org/10.1016/j.clcc.2017.04.004>

<sup>2</sup> Mendelsohn, J., Lazar, V., & Kurzrock, R. (2015). Impact of Precision Medicine in Diverse Cancers: A Meta-Analysis of Phase II Clinical Trials. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology*, 33(32), 3817–3825. <https://doi.org/10.1200/JCO.2015.61.5997>

66% of oncology providers reported that insurance coverage for biomarker testing is a significant or moderate barrier to appropriate biomarker testing.<sup>3</sup>

A recent analysis of commercial plan coverage policies for multi-gene panel tests found that 85% of Kentuckians are covered by plans that are more restrictive than National Comprehensive Cancer Network (NCCN) clinical guidelines for biomarker testing in advanced lung, breast, melanoma, and prostate cancers.<sup>4</sup>

**Without action to expand coverage and access to biomarker testing, advances in precision medicine could exacerbate existing disparities in access to care and, consequently, health outcomes associated with race, ethnicity, income, and geography.**

Not all communities are benefiting from the latest advancements in biomarker testing and precision medicine. Communities that have been excluded including communities of color, individuals with lower socioeconomic status, rural residents, and patients receiving care in non-academic medical centers are less likely to receive guideline-indicated biomarker testing.<sup>5,6,7,8,9,10</sup>

We urge your support for [BILL NUMBER] so that more Kentuckians can benefit from biomarker testing supported by the latest medical and scientific evidence.

Please don't hesitate to reach out with any questions.

Respectfully submitted,



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<sup>3</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)

<sup>4</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>5</sup> Kehl, K. L., Lathan, C. S., Johnson, B. E., & Schrag, D. (2019). Race, Poverty, and Initial Implementation of Precision Medicine for Lung Cancer. *Journal of the National Cancer Institute*, 111(4), 431–434. <https://doi.org/10.1093/jnci/diy202>.

<sup>6</sup> Presley, C., Soulos, P., Chiang, A., Longtine, J., Adelson, K., Herbst, R., Nussbaum, N., Sorg, R., Abernethy, A., Agarwala, V., & Gross, C. (2017). Disparities in next generation sequencing in a population-based community cohort of patients with advanced non-small cell lung cancer. *Journal of Clinical Oncology*. 35. 6563-6563. 10.1200/JCO.2017.35.15\_suppl.6563.

<sup>7</sup> Lamba, N., & Iorgulescu, B. (2020). Disparities in microsatellite instability/mismatch repair biomarker testing for patients with advanced colorectal cancer. *Cancer Epidemiol Biomarkers Prev* December 1 2020 (29) (12 Supplement) PO-091; DOI: 10.1158/1538-7755.DISP20-PO-091.

<sup>8</sup> Norris, R. P., Dew, R., Sharp, L., Greystoke, A., Rice, S., Johnell, K., & Todd, A. (2020). Are there socio-economic inequalities in utilization of predictive biomarker tests and biological and precision therapies for cancer? A systematic review and meta-analysis. *BMC medicine*, 18(1), 282. <https://doi.org/10.1186/s12916-020-01753-0>.

<sup>9</sup> Kim, E. S., Roy, U. B., Ersek, J. L., King, J., Smith, R. A., Martin, N., Martins, R., Moore, A., Silvestri, G. A., & Jett, J. (2019). Updates Regarding Biomarker Testing for Non-Small Cell Lung Cancer: Considerations from the National Lung Cancer Roundtable. *Journal of thoracic oncology : official publication of the International Association for the Study of Lung Cancer*, 14(3), 338–342. <https://doi.org/10.1016/j.jtho.2019.01.002>

<sup>10</sup> F. R., Kerr, K. M., Bunn, P. A., Jr, Kim, E. S., Obasaju, C., Pérol, M., Bonomi, P., Bradley, J. D., Gandara, D., Jett, J. R., Langer, C. J., Natale, R. B., Novello, S., Paz-Ares, L., Ramalingam, S. S., Reck, M., Reynolds, C. H., Smit, E. F., Socinski, M. A., Spigel, D. R., ... Thatcher, N. (2018). Molecular and Immune Biomarker Testing in Squamous-Cell Lung Cancer: Effect of Current and Future Therapies and Technologies. *Clinical lung cancer*, 19(4), 331–339. <https://doi.org/10.1016/j.clcc.2018.03.014>