



June 7, 2022

Dear Legislators,

On behalf of the millions of patients and health care providers we represent in every state, we ask you to support Assemblywoman Hunter’s model legislation on biomarker testing as introduced.

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

Precision medicine uses biomarker testing to gather information about a person’s own body to prevent, diagnose, or treat disease.<sup>1</sup> This information is found by testing a patient’s tissue, blood, or other biospecimen for the presence of a biomarker (e.g., genetic alterations, molecular signatures). 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.

<sup>1</sup> NCI Dictionary of Cancer Terms. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/precision-medicine>. Accessed September 7, 2020.

**Research shows that targeted therapy can improve health outcomes, increase quality of life, and prolong patient survival.<sup>2,3</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.**

**Our organizations wholeheartedly endorse Assemblywoman Hunter’s proposed model legislation, which will align insurance coverage of biomarker testing with the latest medical evidence.**

- This language has been thoroughly vetted and received **bipartisan support in several states.**
- Comparable legislation has **passed in Illinois and Arizona with overwhelming support<sup>4,5</sup>** and is currently under consideration in **California, Ohio, and Rhode Island.**
- With more progress in this area to come, **NCOIL’s adoption of the existing consensus language will help further patient access to the testing necessary to inform the best treatment of individual patients.**

As the science of biomarker-driven treatments is quickly evolving, clinical treatment guidelines – which are developed and updated regularly based on rigorous evaluation of clinical evidence – provide an essential resource to help health care providers provide the best care informed by the latest evidence.

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, 66% of oncology providers reported that insurance coverage for biomarker testing is a significant or moderate barrier to appropriate biomarker testing.<sup>6</sup> A recent analysis of commercial plan coverage policies for multi-gene panel tests found that 71% are more restrictive than National Comprehensive Cancer Network (NCCN) clinical guidelines for advanced lung, breast, melanoma, and prostate cancers.<sup>7</sup>

Insurance coverage for medically appropriate biomarker testing is failing to keep pace with innovations and advancements in treatment. We must work to remove barriers to biomarker testing to ensure that patients can unlock the value and cost-savings potential of precision medicine. **Our organizations support expanding appropriate coverage of biomarker testing for public and private insurance plans, as Assemblywoman Hunter’s proposed legislation does.**

**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

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<sup>2</sup> Gutierrez, M. E., Choi, K., Lanman, R. B., Licita, 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>3</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>

<sup>4</sup> <https://www.ilga.gov/legislation/BillStatus.asp?DocNum=1779&GAID=16&DocTypeID=HB&SessionID=110&GA=102>

<sup>5</sup> <https://legiscan.com/AZ/votes/HB2144/2022>

<sup>6</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>7</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.

socioeconomic status, rural residents, and patients receiving care in non-academic medical centers are less likely to receive guideline-indicated biomarker testing.<sup>8,9,10,11,12,13</sup>

Despite the clear benefits of biomarker testing, many insurance plans do not cover evidence-based biomarker testing for all patients who need it. Improving coverage for and access to biomarker testing across insurance types is key to reducing health disparities. We must remove barriers to biomarker testing and precision medicine, and ensure all patients, regardless of race, ethnicity, gender, age, sexual orientation, socioeconomic status or zip code, benefit from better care.

If you have any questions about this legislation or biomarker testing more generally, please reach out to Hilary Gee Goeckner at [Hilary.Gee@cancer.org](mailto:Hilary.Gee@cancer.org).

Sincerely,

**ALS Association**

**American Cancer Society Cancer Action Network**

**American Lung Association**

**American Kidney Fund**

**Arthritis Foundation**

**Be the Match/National Marrow Donor Program**

**Cancer Support Community**

**Exon 20 Group**

**Fight Colorectal Cancer**

**Global Colon Cancer Association**

**Go2 Foundation for Lung Cancer**

**Head and Neck Cancer Alliance**

**HEAL Collaborative**

**International Foundation for Autoimmune & Autoinflammatory Arthritis (AIA)**

**ICAN, International Cancer Advocacy Network**

**Infusion Access Foundation**

**KRAS Kickers**

**Lung Cancer Research Foundation**

**LUNGevity Foundation**

**National Comprehensive Cancer Network (NCCN)**

**National Organization for Rare Diseases**

**National Ovarian Cancer Coalition**

**Oncology Nursing Society**

**Patients Rising**

**Susan G. Komen**

**TargetCancer Foundation**

**Triage Cancer**

**Zero – The End of Prostate Cancer**

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<sup>8</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/djy202>.

<sup>9</sup> Presley, C., Soulos, P., Chiang, A., Longline, 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](https://doi.org/10.1200/JCO.2017.35.15_suppl.6563).

<sup>10</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>11</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>12</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>13</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>