

















































September 1, 2022

Dear Governor Newsom,

On behalf of the patients and health care providers we represent across California, we urge you to sign SB 912.

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. 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.

Research shows that targeted therapy can improve health outcomes, increase quality of life, and prolong patient survival.^{ii,iii}

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.

SB 912 aligns insurance coverage of biomarker testing with the latest medical evidence.

This language has been thoroughly vetted and received **broad support from patients**, **providers**, **industry**, **and lawmakers**. Comparable legislation has passed and signed into law in Arizona, Illinois, Louisiana, and Rhode Island with overwhelming bipartisan support.

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.^{iv} A recent analysis of commercial plan coverage policies for multi-gene panel tests found that 35% of Californians are covered by policies that are more restrictive than National Comprehensive Cancer Network (NCCN) clinical guidelines for advanced lung, breast, melanoma, and prostate cancers.^v

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 California 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. Vi,Vii,Viii,i,ix,x,xi

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. SB 912 will help remove barriers to biomarker testing to ensure that patients can unlock the value and cost-savings potential of precision medicine.

If you have any questions about this legislation, please reach out to Autumn Ogden-Smith, California State Legislation Director with the American Cancer Society Cancer Action Network, at autumn.ogden@cancer.org. Sincerely,

ALS Association
American Cancer Society Cancer Action Network
American Lung Association
Arthritis Foundation
Be The Match/National Marrow Donor Program
CancerCare
CLL Society
Exon20 Group
Fight Colorectal Cancer
Global Colon Cancer Association
Go2 Foundation
ICAN - International Cancer Advocacy Network
Infusion Access Foundation

International Foundation for Autoimmune &
Autoinflammatory Arthritis (AiA)
KRAS Kickers
Lung Cancer Research Foundation
LUNGevity Foundation
Melanoma Research Foundation
National Comprehensive Cancer Network® (NCCN®)
National Organization for Rare Diseases
National Ovarian Cancer Coalition
Patients Rising Now
PD1 Amplified
Susan G. Komen
Triage Cancer
ZERO: The End of Prostate Cancer

- vii 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.
- viii Lamba, N., & lorgulescu, 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.
- ^{ix} 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.
- * 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
- xi 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.cllc.2018.03.014

NCI Dictionary of Cancer Terms, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/precision-medicine.

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.cllc.2017.04.004 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

^{iv} ACS CAN. "Survey Findings Summary: Understanding Provider Utilization of Cancer Biomarker Testing Across Cancers." Dec, 2021.

https://www.fightcancer.org/sites/default/files/national_documents/provider_utilization_of_biomarker_testing_polling_memo_dec_20 21.pdf

^v 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.

vi 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.