

THE NATIONAL HISPANIC CAUCUS OF STATE LEGISLATORS

## RESOLUTION No. 2021-21

## Recognizing the Importance of Precision Medicine and Biomarker Testing

Reported to the Caucus by the NHCSL Healthcare Task Force Rep. Alma Hernández (AZ), Chair

Sponsored by Rep. Alma Hernández (AZ)

Ratified by the Caucus on March 26, 2022

**WHEREAS,** precision medicine, which is also called personalized health care or individualized medicine, is an evolving field in which health care providers use analysis of a patient's biospecimen, known as biomarker testing, to determine which medical treatments will work best for each patient;<sup>1</sup> and,

**WHEREAS,** by combining the data from biomarker testing with an individual's medical history and circumstances, health care providers can direct a patient to targeted treatment, which benefits both patients and the overall health care system;<sup>2</sup> and,

<sup>&</sup>lt;sup>1</sup> National Cancer Institute Dictionary of Cancer Terms.

https://www.cancer.gov/publications/dictionaries/cancer-terms/def/precision-medicine <sup>2</sup> American Cancer Society Cancer Action Network, Improving Access to Biomarker Testing:

Advancing Precision Medicine in Cancer Care. Sep. 2020. https://www.fightcancer.org/sites/default/files/Improving%20Access%20to%20Biomarker%20Te sting.pdf

**WHEREAS,** the field of precision medicine holds great promise in ensuring the delivery of the right treatment to the right patient at the right time and to avoid the cost and potential negative side-effects of treatments that would not help;<sup>3</sup> and,

**WHEREAS,** 60 percent of treatments in preclinical development rely on biomarker data;<sup>4</sup> and,

**WHEREAS,** biomedicine and the understanding of the characteristics of a patient's disease that informs precision medicine is evolving rapidly; and,

**WHEREAS,** health care providers are increasingly utilizing technologies, such as biomarker testing, that can help identify gene mutations, alterations, or protein expressions specific to individual patients; and,

**WHEREAS,** health outcomes can be improved through the use of precision medicine, for example, patients with certain types of lung cancer who received biomarker testing had a 31 percent reduction in mortality;<sup>5</sup> and,

WHEREAS, while oncology has been leading the way in precision medicine advancements, the tailoring of treatment to specific biomarkers is being explored in other diseases and conditions; and,

WHEREAS, cancer is the leading cause of death for Hispanics in the United States;<sup>6</sup> and,

**WHEREAS,** Hispanic cancer patients are less likely than non-Hispanic whites to be diagnosed at early stage disease for many cancers;<sup>7</sup> and,

**WHEREAS,** there are notable racial, ethnic and other socioeconomic disparities in access to and utilization of biomarker testing;<sup>8</sup> and,

<sup>3</sup> Biomarker Testing Can Direct Care, but Only If Clinicians Perform the Right Tests. Evidence-Based Oncology, February 2020, Volume 26, Issue 2. <u>https://www.ajmc.com/view/biomarker-testing-candirect-care-but-only-if-clinicians-perform-the-right-tests</u>. And see, 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

<sup>6</sup> <u>https://www.cancer.org/research/cancer-facts-statistics/hispanics-latinos-facts-figures.html</u> <sup>7</sup> <u>https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/cancer-facts-and-figures-for-hispanics-and-latinos/cancer-facts-and-figures-for-hispanics-and-latinos-2018-2020.pdf</u>

<sup>&</sup>lt;sup>4</sup> <u>https://www.thejournalofprecisionmedicine.com/the-journal-of-precision-medicine/special-</u> report-the-evolution-of-biomarker-use-in-clinical-trials-for-cancer-treatments/

<sup>&</sup>lt;sup>5</sup> <u>https://www.modernhealthcare.com/technology/importance-comprehensive-biomarker-testing-improve-patient-outcomes-advanced-non-small</u>

<sup>&</sup>lt;sup>8</sup> See 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. <u>https://doi.org/10.1093/jnci/djv202.</u> See also 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. And see, Norris, R. P., Dew, R., Sharp,

**WHEREAS,** access to biomarker testing is closely related to insurance coverage.<sup>9</sup> Compared to non-Hispanic whites, Hispanics are more likely to be uninsured and, those who are, are less likely to have private insurance;<sup>10</sup> and,

WHEREAS, colorectal cancer patients who are older, uninsured, or Medicaid-insured, are less likely to receive guideline-indicated biomarker testing;<sup>11</sup> and,

WHEREAS, without efforts to increase access to biomarker testing and precision medicine for groups that have been marginalized, disparities in cancer survival could increase; and,

**WHEREAS,** the National Academy of Medicine considers biomarker tests to be "key to unlocking the promise" of precision medicine;<sup>12</sup> and,

**WHEREAS,** biomarker testing is available for an ever-increasing range of conditions and diseases, but patient access to these tests is not keeping pace with the rate of innovation, even for those with private insurance;<sup>13</sup> and,

**WHEREAS,** a lack of awareness among providers and patients, a lack of common terminology, and deficient coverage policies by both public and private payers are preventing effective adoption and integration of biomarker testing into precision medicine particularly for communities of color and in nonacademic health care settings;<sup>14</sup> and,

https://www.ncbi.nlm.nih.gov/books/NBK379335/

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. <u>https://doi.org/10.1186/s12916-020-01753-0</u>.

<sup>&</sup>lt;sup>9</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>&</sup>lt;sup>10</sup> Hispanics are second only to American Indians and Alaska Natives in lacking private health insurance coverage. <u>https://www.kff.org/racial-equity-and-health-policy/issue-brief/health-coverage-by-race-and-ethnicity/</u>

<sup>&</sup>lt;sup>11</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>&</sup>lt;sup>12</sup> Committee on Policy Issues in the Clinical Development and Use of Biomarkers for Molecularly Targeted Therapies; Board on Health Care Services; Institute of Medicine; National Academies of Sciences, Engineering, and Medicine; Graig LA, Phillips JK, Moses HL, editors. Biomarker Tests for Molecularly Targeted Therapies: Key to Unlocking Precision Medicine. Washington (DC): National Academies Press (US); 2016 Jun 30. 1, Introduction. Available from:

<sup>&</sup>lt;sup>13</sup> American Cancer Society Cancer Action Network, Improving Access to Biomarker Testing: Advancing Precision Medicine in Cancer Care. Sep. 2020.

https://www.fightcancer.org/sites/default/files/Improving%20Access%20to%20Biomarker%20Te sting.pdf

<sup>&</sup>lt;sup>14</sup> Ibid.

**WHEREAS**, states can promote appropriate awareness<sup>15</sup> and education about the ways biomarker testing can be used to support diagnosis, treatment, and monitoring of patients in a personalized way; and,

**WHEREAS,** states and the Centers for Medicare and Medicaid Services (CMS) can also mandate coverage<sup>16</sup> for biomarker testing and precision medicine, or lower barriers to access,<sup>17</sup> in plans or policies which they regulate.

**THEREFORE BE IT RESOLVED,** that the National Hispanic Caucus of State Legislators calls on states to raise awareness, encourage education, and improve understanding of the ways biomarker testing can be used to support diagnosis, treatment, and monitoring of patients in a personalized way; and,

**BE IT FURTHER RESOLVED,** that the National Hispanic Caucus of State Legislators calls on the Centers for Medicare and Medicaid Services (CMS), on the federal government as a whole, and on states to approve rules and/or enact legislation to ensure equal, fairly priced access to biomarker testing and precision medicine with a focus on eliminating the racial, ethnic and other socioeconomic disparities that have plagued the field up to now.

THE NATIONAL HISPANIC CAUCUS OF STATE LEGISLATORS UNANIMOUSLY RATIFIED THIS RESOLUTION ON MARCH 26, 2022, AT ITS ANNUAL MEETING IN WASHINGTON, DC.

<sup>&</sup>lt;sup>15</sup> For example, the Illinois General Assembly <u>declared</u> March 2021 as "Precision Medicine and Biomarker Testing Awareness Month." The Iowa Legislature did the <u>same</u> for every month of March, starting in 2022.

<sup>&</sup>lt;sup>16</sup> For example, the Arizona House has approved <u>H.B. 2144</u> (pending Senate approval as of this writing) which requires, on or after January 1, 2023, all health subscription contracts, evidences of coverage and policies, including the Arizona Health Care Cost Containment System (AHCCCS), to cover biomarker testing for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of a subscriber's, enrollee's or insured's disease or condition to guide treatment decisions, in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples, when the test is supported by medical and scientific evidence including when approved or cleared by the Food and Drug Administration (FDA), or indicated for an approved drug, when indicated nationally or locally by Medicare, or when nationally recognized by clinical practice guidelines and consensus statements.

<sup>&</sup>lt;sup>17</sup> For example, the California Legislature (<u>SB 535</u> by Monique Limón) prohibits all health care service plan contracts or health insurance policies (including the California Medicaid system Medi-Cal) issued, amended or renewed on or after July 1, 2022, from requiring prior authorization for biomarker testing for an enrollee or insured with advanced or metastatic stage 3 or 4 cancer, or its progression or recurrence. The Illinois General Assembly <u>requires</u> the same for every individual or group health care service plan issued or renewed on or after January 1, 2022.