



STATE OF HAWAII | KA MOKU'ĀINA 'O HAWAI'I
OFFICE OF THE DIRECTOR
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS

NADINE Y. ANDO
DIRECTOR | KA LUNA HO'OKELE

JOSH GREEN, M.D.
GOVERNOR | KE KIA'ĀINA
SYLVIA LUKE
LIEUTENANT GOVERNOR | KA HOPE KIA'ĀINA

DEAN I. HAZAMA
DEPUTY DIRECTOR | KA HOPE LUNA HO'OKELE

KA 'OIHANA PILI KĀLEPA
335 MERCHANT STREET, ROOM 310
P.O. BOX 541
HONOLULU, HAWAII 96809
Phone Number: (808) 586-2850
Fax Number: (808) 586-2856
cca.hawaii.gov

Testimony of the Department of Commerce and Consumer Affairs

Before the
House Committees on Health and Human Services & Homelessness
Friday, January 31, 2025
9:00 a.m.

State Capitol, Conference Room 329 & via Videoconference

On the following measure:
H.B. 553, RELATING TO INSURANCE

Chairs Takayama, Martin, and Members of the Committees:

My name is Gordon Ito, and I am the Insurance Commissioner for the Department of Commerce and Consumer Affairs' (Department) Insurance Division. The Department offers comments on this bill.

The purpose of this bill is to, beginning 1/1/2026, require health insurers, mutual benefit societies, health maintenance organizations, and health plans under the State's Medicaid managed care program to provide coverage for biomarker testing.

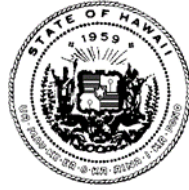
We note that it is unclear whether the amendments in sections 1 through 3 of this bill, which require health plans to provide benefits for biomarker testing, would be construed as "in addition to the essential health benefits" within the meaning of 45 Code of Federal Regulations (CFR) § 155.170(a), or subject to defrayment provisions under 45 CFR § 155.170(b) which apply to benefits "in addition to the essential health benefits."

For the Committee's information, Hawaii Revised Statutes section 23-51 provides, in part, that "[b]efore any legislative measure that mandates health insurance coverage for specific health services, specific diseases, or certain providers of health care services as part of individual or group health insurance policies, [sic] can be considered, there shall be concurrent resolutions passed requesting the auditor to prepare and submit to the legislature a report[.]" Although the auditor did complete Report No. 25-01, "Assessment of Proposed Mandatory Health Insurance Coverage for Medically Necessary Biomarker Testing," the Department notes that the auditor's report was based on House Bill No. 2223, House Draft 1, Regular Session 2024 (HB 2223, HD1), which contain substantial differences from this bill.

Finally, The Department notes that section 1, page 2, lines 13 to 16 contains a provision that states, "If a policy restricts coverage under this section, the patient and prescribing health care provider shall be provided access to a clear, readily accessible, and convenient process for requesting an exception." The use of the term "policy" as used in this section is not defined and is unclear as to which policy would restrict coverage. Additionally, the Department is unclear how the process to request an exception in both sections 1 and 2 of the bill would operate with section 432E-5, Hawaii Revised Statutes, which requires that a health carrier shall establish and maintain a procedure to provide for the resolution of an enrollee's complaints and internal appeals.

Thank you for the opportunity to testify on this bill.

JOSH GREEN, M.D.
GOVERNOR
KE KIA'ĀINA



RYAN I. YAMANE
DIRECTOR
KA LUNA HO'OKELE

JOSEPH CAMPOS II
DEPUTY DIRECTOR
KA HOPE LUNA HO'OKELE

STATE OF HAWAII
KA MOKU'ĀINA O HAWAI'I
DEPARTMENT OF HUMAN SERVICES
KA 'OIHANA MĀLAMA LAWELawe KANAKA
Office of the Director
P. O. Box 339
Honolulu, Hawaii 96809-0339

TRISTA SPEER
DEPUTY DIRECTOR
KA HOPE LUNA HO'OKELE

January 29, 2025

TO: The Honorable Representative Gregg Takayama, Chair
House Committee on Health

The Honorable Representative Lisa Marten, Chair
House Committee on Human Services & Homelessness

FROM: Ryan I. Yamane, Director

SUBJECT: **HB 553 – RELATING TO INSURANCE.**

Hearing: January 31, 2025, 9:00 a.m.
Conference Room 329 & via Videoconference, State Capitol

DEPARTMENT'S POSITION: The Department of Human Services (DHS) appreciates the intent, offers comments, and respectfully requests an amendment.

PURPOSE: Beginning 1/1/2026, requires health insurers, mutual benefit societies, health maintenance organizations, and health plans under the State's Medicaid managed care program to provide coverage for biomarker testing.

DHS recognizes the importance of the rapidly evolving biomarking testing for targeted diagnosis, treatment, and management of various diseases in recent years. All of the Med-QUEST Medicaid managed care plans currently cover this testing when medically necessary. This aligns with the findings of the State Auditor's report to the Legislature, "Assessment of Proposed Mandatory Health Insurance Coverage For Medically Necessary Biomarker Testing; A Report to the Governor and the Legislature of the State of Hawai'i; Report No. 25-01; January 2025." The Auditor concluded that mandated coverage for medically necessary biomarker

January 29, 2025

Page 2

testing services is redundant of the coverage already required by Hawai'i's Patients' Bill of Rights and Responsibilities Act, specifically, section 432E-1.4, Hawaii Revised Statutes.

The bill also requires DHS to submit State Plan Amendments to cover medically necessary biomarking testing. However, as biomarking testing is already a covered service using the medically necessary standard, no State Plan Amendments are needed. Thus, section 5 mandating a) reimbursement for the medically necessary services of biomarker testing by all health plans under the States's Medicaid managed care program, and b) state plan amendment to be submitted, are redundant and unnecessary. Therefore, DHS respectfully requests an amendment deleting Section 5 from this bill.

Thank you for the opportunity to provide comments on this measure.

Testimony of
John M. Kirimitsu
Counsel

Before:
House Committee on Health
The Honorable Gregg Takayama, Chair
The Honorable Sue L. Keohokapu-Lee Loy, Vice Chair
and
House Committee on Human Services & Homelessness
The Honorable Lisa Marten, Chair
The Honorable Ikaika Olds, Vice Chair

January 31, 2025
9:00 am
Conference Room 329

Re: HB 553 Relating to Insurance

Chairs, Vice Chairs, and committee members, thank you for this opportunity to provide testimony on HB 553 mandating coverage for biomarker testing.

Kaiser Permanente Hawaii would like to offer comments.

Kaiser supports biomarker testing to determine the best treatment options for patients, but believes that this mandate is unnecessary. In the 2025 State Auditor's Report No. 25-01 "*Assessment of Proposed Mandatory Health Insurance Coverage For Medically Necessary Biomarker Testing*" it was reported that:

We found that biomarker testing is already included in health insurance policies issued in Hawai'i. The bill's mandated coverage for medically necessary biomarker testing services is redundant of the coverage already required by Hawai'i's Patients' Bill of Rights and Responsibilities Act.

In that report, the state auditor concluded: **"For the reasons explained above, we conclude that the coverage that HB 2223, HD 1 seeks to mandate is already mandated by existing law and already provided by Hawai'i's plan providers."**

A copy of the state auditor's report can be found at <https://files.hawaii.gov/auditor/Reports/2025/25-01.pdf>

Should this bill move forward, Kaiser requests an amendment on Page 1, lines 4-12, to include the nationally recognized "medically necessary" standard, which will ensure that the biomarker treatment is within the accepted standards in the medical community and also prevent coverage for unnecessary tests that increase costs without improving care (added language is [bracketed]):

"§431:10A- Biomarker testing; coverage. (a) Each individual or group policy of accident and health or sickness insurance issued or renewed in the State on or after January 1, 2026, shall provide coverage for [medically necessary] biomarker testing for the policyholder, or any dependent of the policyholder who is covered by the policy, for purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an insured person's disease or condition, or to guide treatment decisions when supported by medical and scientific evidence, including:

Thank you for the opportunity to comment.



**Alliance for
Patient Access**

January 30, 2025

The Honorable Gregg Takayama
House Committee on Health
Committee Chair
State Capitol, 415 South Beretania Street
Honolulu, HI 96813

The Honorable Lisa Marten
House Committee on Human Services & Homelessness
Committee Chair
State Capitol, 415 South Beretania Street
Honolulu, HI 96813

RE: SUPPORT for HB 553 - Biomarker Testing Coverage

To Chair Takayama & Chair Marten:

On behalf of the Alliance for Patient Access (AfPA), I am writing to urge your support for HB 553, which would expand and simplify health insurance coverage for biomarker testing. This bill requires coverage for biomarker testing for the purposes of diagnosis, treatment, prognosis, management and ongoing monitoring of a patient's disease.

Founded in 2006, AfPA is a national network of policy-minded health care providers who advocate for patient-centered care. AfPA supports health policies that reinforce clinical decision-making, promote personalized care and protect the provider-patient relationship. Motivated by these principles, AfPA members participate in clinician working groups, advocacy initiatives, stakeholder coalitions and the creation of educational materials.

Health care is rapidly moving towards an advanced, precision-based approach. For example, with the advancements of precision medicine in oncology care, doctors can offer cancer patients targeted treatments based on the molecular understanding of their disease, allowing for more personalized, patient-centered care. This can lead to more effective treatment, with fewer side effects – and has been proven to improve patient outcomes for some types of cancer.¹

This type of individualized treatment is possible by knowing the specific genomic alterations in the patient, which can only be detected through biomarker testing. Advances in precision medicine are also being seen in a number of disease states including rheumatology, neurology and mental health. For example, a recent study highlighted that a simple blood biomarker test was found to be up to 96% accurate in identifying the most important biomarker in Alzheimer's disease pathology.² Similarly in rheumatology, biomarkers reveal whether specific medications such as TNF inhibitors would be ineffective for patients who have been diagnosed with rheumatoid arthritis.³

Biomarker testing can reduce the number of time-consuming and costly tests used to determine a patient's diagnosis, as a biomarker analysis will provide insight as to whether a targeted or specific treatment might work for a specific patient. This could be lifesaving for countless patients. However, **without insurance coverage of biomarker testing, patients would face delays in**

¹ <https://ascopubs.org/doi/full/10.1200/jop.2016.011486?cookieSet=1>

² [doi:10.1001/jamaneurol.2023.5319](https://doi.org/10.1001/jamaneurol.2023.5319)

³ <https://www.hcplive.com/view/wesley-mizutani-md-sb-496-expands-insurance-coverage-for-biomarkers>

identifying the best treatment options and risk experiencing significantly worse disease outcomes.

Unfortunately, patients in Hawaii face insurance coverage barriers for both biomarker testing and individualized treatments. This can cause delays in care that can be devastating for patients with diseases like advanced cancer. HB 553 will ensure that patients will have equal access, regardless of their disease stage, to biomarker testing by requiring appropriate coverage. Promoting early detection and faster diagnosis, when possible, can lead to life-saving precision treatment.

HB 553 supports the clinician-patient relationship by allowing clinicians to access appropriate medical tools for their patients and helping ensure patients can access testing. This will support optimal patient care by driving accurate diagnosis and effective treatment decisions. On behalf of the Alliance for Patient Access, I urge your support for HB 553 to ensure Hawaii patients can access the tests and treatments they need. Should you have any questions, please reach out to Casey McPherson at cmcpherson@allianceforpatientaccess.org.

Sincerely,



Josie Cooper
Executive Director
Alliance for Patient Access

Cc:

Rep. Sue L. Keohokapu-Lee Loy
Rep. Terez Amato
Rep. Cory M. Chun
Rep. Ikaika Olds
Rep. Jenna Takenouchi
Rep. David Alcos III
Rep. Diamond Garcia



January 30, 2025

RE: Support for HB553 – An Act to Require Health Insurance Coverage for Biomarker Testing

Dear Honorable Members of the Hawaii House Committee on Health and the Committee on Human Services & Homelessness:

The National Comprehensive Cancer Network® (NCCN®) appreciates the opportunity to comment on HB553, an act relating to coverage for biomarkers testing. Biomarkers Testing is of paramount importance as it relates to NCCN's mission of improving and facilitating, quality, effective, equitable, and accessible cancer care and prevention. NCCN will focus our supportive comments on the importance of comprehensive biomarker testing for residents of Hawaii and the role of clinical practice guidelines in determining appropriate care.

NCCN Background

As an alliance of 33 leading academic cancer centers in the United States, NCCN® is a developer of authoritative information regarding cancer prevention, screening, diagnosis, treatment, and supportive care that is widely used by clinical professionals and payers alike. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) are a comprehensive set of guidelines detailing the sequential management decisions and interventions that currently apply to 97 percent of cancers affecting patients in the United States. NCCN Guidelines® and Library of Compendia products help ensure access to appropriate care and are used by payers representing more than 85% of covered lives in the United States including CMS. NCCN imposes strict policies to shield the guidelines development processes from external influences. The guidelines development is supported exclusively by the Member Institutions' dues and does not accept any form of industry or other external financial support for the guidelines development program. The NCCN Guidelines are updated at least annually in an evidence-based process integrated with the expert judgment of multidisciplinary panels of expert physicians from NCCN Member Institutions. The NCCN Guidelines are transparent, continuously updated, available free of charge online for non-commercial use and are available through a multitude of health information technology (HIT) vendors.

NCCN Biomarkers Compendium®

The NCCN Guidelines® include biomarkers used for the purposes of diagnosis, screening, monitoring, surveillance, prediction, therapeutic decision-making and prognostication. The NCCN Biomarkers Compendium® contains biomarker information derived directly from the NCCN Guidelines to support decision-making around the use of biomarker testing in patients with cancer and is intended to be a resource for payers, providers, and health care entities navigating the rapidly changing evidence base for medically necessary biomarker testing in oncology. Information is provided in a searchable database that is updated continuously in conjunction with the NCCN Guidelines® to remain evergreen. In addition to providing information regarding clinical indication(s) for specific biomarker testing, the NCCN Biomarkers Compendium provides essential details for testing methodologies recommended within the NCCN Guidelines.

Biomarker Testing Impact on Cancer Care Outcomes

Numerous independent studies have found adherence to NCCN Guidelines[®] improves care delivery and outcomes for patients with cancer, including at least one study demonstrating that access to guideline adherent biomarker testing can improve overall survival with appropriately utilized targeted therapy in the first-line setting and later lines of treatment.¹ Guideline adherence for both treatment and biomarker testing has also been shown across numerous studies to decrease costs to payers and patients.^{2,3,4,5} Additionally, the majority of newly approved cancer therapies in recent years were biomarker-specific treatments requiring accompanying biomarker testing to determine their potential role in a given treatment plan.^{6,7} Non-adherence to guidelines has also been identified as a key contributor to inequities in care outcomes across race and ethnicity with some studies finding these disparities greatly reduced or eliminated when guideline adherent care is received.^{8,9} Adherence to nationally-recognized guidelines improves care outcomes including quality of life and overall survival, may reduce inequities in care outcomes, and reduces cost of care to both the payer and the patient.

Despite a wide body of literature supporting the need for guideline adherent biomarker testing, coverage, and access to appropriate biomarker testing is still widely variable leaving many patients unable to access appropriate care. A 2022 study evaluating publicly available insurance policies for biomarker testing found that 71% of plans were more restrictive than NCCN Guideline recommendations.¹⁰ This critical care gap must be addressed to ensure all people can access optimal cancer care. HB553 creates coverage for appropriate biomarker testing that adheres to nationally recognized evidence-based clinical practice guidelines. As such, NCCN is pleased to support HB553.

NCCN Supports Clinically Appropriate Biomarkers Testing

NCCN recommends covering biomarker testing as delineated in evidence-based nationally recognized clinical practice guidelines. NCCN would like to note that the most recent versions of our Guidelines are always available on our website. As NCCN Guidelines[®] and the NCCN Biomarkers Compendium[®] are continuously updated to stay current with the evidence, NCCN encourages your committee to refer to the current recommendations and Guideline versions on the NCCN website as a health policy tool to ensure those decisions are up to date with the standard of care.

NCCN appreciates the opportunity to comment on and support LD107. We are proud to support this legislation in harmony with our coalition partners. As a nationally recognized clinical guidelines organization, NCCN is happy to serve as a resource during the legislative process. We look forward to working together to ensure access to high-quality cancer care.

Sincerely,

Crystal Denlinger, MD, FACP
Chief Executive Officer
National Comprehensive Cancer Network
denlinger@nccn.org 267.622.6654

References

- 1 Aggarwal C, Marmarelis ME, Hwang WT, et al. Association of comprehensive molecular genotyping and overall survival in patients with advanced non-squamous non-small cell lung cancer. *JCO*. 2022;40(16_suppl):9022-9022. doi:10.1200/JCO.2022.40.16_suppl.9022
- 2 Newcomer LN, Weininger R, Carlson RW. Transforming prior authorization to decision support. *Journal of Oncology Practice*. 2017;13(1). doi:10.1200/jop.2016.015198
- 3 Williams CP, Azuero A, Kenzik KM, et al. Guideline discordance and patient cost responsibility in medicare beneficiaries with metastatic breast cancer. *Journal of the National Comprehensive Cancer Network*. 2019;17(10):1221-1228. doi:10.6004/jnccn.2019.7316
- 4 Sapkota U, Cavers W, Reddy S, Avalos-Reyes E, Johnson KA. Total cost of care differences in National Comprehensive Cancer Center (NCCN) concordant and non-concordant breast cancer patients. *JCO*. 2022;40(16_suppl):e18833-e18833. doi:10.1200/JCO.2022.40.16_suppl.e18833
- 5 Sapkota U, Cavers W, Reddy S, Avalos-Reyes E, Johnson KA. Total cost of care differences in National Comprehensive Cancer Center (NCCN) concordant and non-concordant patients with colon cancer. *JCO*. 2022;40(16_suppl):3624-3624. doi:10.1200/JCO.2022.40.16_suppl.3624
6. York OH PharmD, MPH, BCPS, BCGP Professor, Department of Pharmacy Practice St John's University College of Pharmacy & Health Sciences Queens, New. Trends in FDA-Approved Cancer Therapies. www.uspharmacist.com. <https://www.uspharmacist.com/article/trends-in-fdaapproved-cancer-therapies>
7. Suehnholz SP, Kundra R, Zhang H, et al. Tracking the FDA precision oncology drug approval landscape in OncoKB. *Journal of Clinical Oncology*. 2024;42(16_suppl):e13507-e13507. doi:https://doi.org/10.1200/jco.2024.42.16_suppl.e13507
8. Fang P, He W, Gomez D, Hoffman KE, Smith BD, Giordano SH, Jagsi R, Smith GL. Racial disparities in guideline-concordant cancer care and mortality in the United States. *Adv Radiat Oncol*. 2018 May 4;3(3):221-229. doi: 10.1016/j.adro.2018.04.013. PMID: 30202793; PMCID: PMC6128037.
9. Blom EF, Ten Haaf K, Arenberg DA, de Koning HJ. Disparities in Receiving Guideline-Concordant Treatment for Lung Cancer in the United States. *Ann Am Thorac Soc*. 2020 Feb;17(2):186-194. doi: 10.1513/AnnalsATS.201901-094OC. PMID: 31672025; PMCID: PMC6993802.
- 10, 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. *Personalized Medicine*. 2022;19(3):171-180. doi:10.2217/pme-2021-0174



House Committee on Health
Rep. Gregg Takayama, Chair
Rep. Sue L. Keohokapu-Loy, Vice Chair

House Committee on Human Services and Homelessness
Rep. Lisa Marten, Chair
Rep. Ikaika Olds, Vice Chair

Hearing Date: Friday, January 31, 2025

ACS CAN IN STRONG SUPPORT FOR HB 553 – RELATING TO INSURANCE.

Cynthia Au, Government Relations Director – Hawai‘i Guam
American Cancer Society Cancer Action Network

Thank you for the opportunity to testify in STRONG **SUPPORT** of HB 553: Relating to Insurance.

The American Cancer Society Cancer Action Network (ACS CAN) writes to you today in strong support of HB 553. We ask you and the members of your committee to pass this critical legislation that will improve patient access to care. Timely access to guideline-indicated comprehensive biomarker testing will enable more patients to access the most effective treatments for their disease and can potentially help achieve the triple aim of health care: better health outcomes, improved quality of life^{1,2} and reduced costs.^{3,4,5}

¹ 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>

² 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>

³ Brito RA, Cullum B, Hastings K, et al. Total cost of lung cancer care associated with broad panel versus narrow panel sequencing. *Journal of Clinical Oncology* 2020; 38, no. 15_suppl; 7077. https://ascopubs.org/doi/abs/10.1200/JCO.2020.38.15_suppl.7077

⁴ 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.

⁵ 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>

This legislation will ensure the people of Hawaii covered by Medicaid and state regulated insurance plans have coverage for biomarker testing when medically appropriate. Progress in improving cancer outcomes increasingly involves the use of precision medicine, which uses information about a person’s own genes or proteins to more accurately diagnose or treat diseases like cancer. Biomarker testing analyzes tissue, blood, or other biospecimen to identify mutations that may impact treatment decisions. This testing is an important step to accessing precision medicine which includes targeted therapies that can lead to improved survivorship and better quality of life for cancer patients. There is currently limited and disparate access to biomarker testing.^{6,7,8} According to a recent survey of oncology providers, 66% reported that insurance coverage is a significant or moderate barrier to appropriate biomarker testing for their patients.⁹

Improving access to biomarker testing and thereby access to targeted therapies is a strategy to reduce health disparities and improve outcomes for cancer patients. A recent peer-reviewed study found that 64% of Hawaii policies reviewed were “more restrictive” than NCCN guidelines for biomarker testing for advanced breast, non-small cell lung cancer, melanoma and prostate cancer.¹⁰ This is evidence that there are Hawaiians who could benefit from biomarker testing that are likely being left behind due to inadequate coverage policies. Not all communities are benefiting from the latest advancements in biomarker testing and precision medicine. Communities that have been marginalized including communities of color and individuals with lower socioeconomic status are less likely to receive biomarker testing. People in rural communities and those receiving care in nonacademic medical centers are also less likely to benefit from biomarker testing.^{11,12} One jarring example of the current disparities in access to

⁶ 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](https://doi.org/10.1200/JCO.2017.35.15_suppl.6563).

⁷ 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>.

⁸ 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>.

⁹ 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_2021.pdf

¹⁰ 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 May;19(3):171-180. doi: 10.2217/pme-2021-0174. Epub 2022 Feb 4. PMID: 35118882.

¹¹ 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>

¹² 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>

biomarker testing: a recent study showing patients with Medicaid diagnosed with advanced non-small cell lung cancer are not only at a 19% higher risk of not receiving biomarker testing and a 30% higher risk of not benefiting from precision medicine; they also have a 23% higher risk of mortality when compared to commercially insured patients.¹³ Ensuring equitable access to biomarker testing by improving coverage for and access to testing across insurance types is key to reducing health disparities. Indeed, without action like this to expand coverage for biomarker testing – including Medicaid – advances in precision oncology could increase existing health disparities.¹⁴

To make sure more Hawaii patients have the access they need to this game changing testing, the legislature should ensure that necessity is determined by doctors and the latest evidence, not insurance companies. This legislation is designed to align the evidence that plans follow in determining which patients can access biomarker testing. The legislation already establishes limits on circumstances when testing should be covered and the evidence that must be demonstrated in order for testing to qualify for coverage. To date, 20 other states including California, Arizona, New Mexico, Texas and New York, have enacted similar laws aligning insurance coverage of biomarker testing with the latest medical and scientific evidence across disease types. HB 553 would make it possible for more patients to get the right treatment at the right time.

Should you have any questions, please do not hesitate to contact Government Relations Director Cynthia Au at Cynthia.Au@Cancer.org or 808.460.6109.

¹³ Gross CP, Meyer CS, Ogale S, Kent M, Wong WB. Associations Between Medicaid Insurance, Biomarker Testing, and Outcomes in Patients With Advanced NSCLC. *J Natl Compr Canc Netw*. 2022;20(5):479-487.e2. doi:10.6004/jnccn.2021.7083

¹⁴ Huey RW, Hawk E, Offodile AC 2nd. Mind the Gap: Precision Oncology and Its Potential to Widen Disparities. *J Oncol Pract*. 2019 Jun;15(6):301-304. doi: 10.1200/JOP.19.00102. Epub 2019 May 21. PMID: 31112478.

EXPAND ACCESS TO BIOMARKER TESTING IN HAWAII

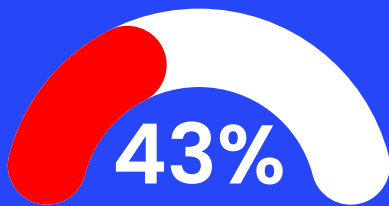
THE RIGHT TREATMENT AT THE RIGHT TIME

WHAT IS BIOMARKER TESTING?

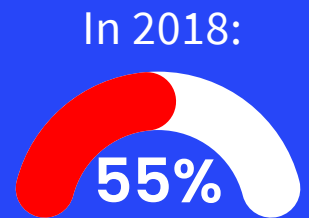
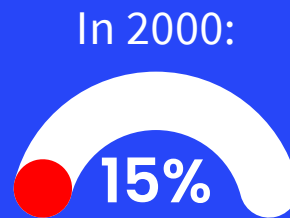
Biomarker testing is often used to help determine the best treatment for a patient.

- It is the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker.
- Biomarker testing is an important step for accessing precision medicine, including targeted therapies that can lead to improved survivorship and better quality of life for cancer patients.
- While most current applications of biomarker testing are in oncology and autoimmune disease, there is research underway to benefit patients with other conditions including heart disease, Alzheimer's disease, and other neurological conditions, rare disease, infectious disease and respiratory illness.

THE IMPORTANCE OF BIOMARKER TESTING



Of the 198 oncology drugs approved between 1998 and 2022 require biomarker testing prior to use¹



Of cancer clinical trials involved biomarkers²

BIOMARKER TESTING & HEALTH EQUITY

- **Not all communities in Hawaii are benefiting from the latest advances in biomarker testing and precision medicine.**
 - Patients who are older, non-white, uninsured or Medicaid-insured, are less likely to be tested for certain guideline-indicated biomarkers.
 - There are lower rates of testing in community settings versus academic medical centers.

THE BOTTOM LINE

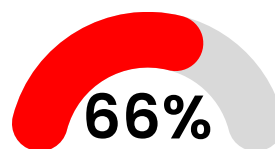
Access to appropriate biomarker testing may help to achieve:

- better health outcomes
- improved quality of life
- reduced costs

Insurance coverage for biomarker testing is failing to keep pace with innovation and advancement in treatment.

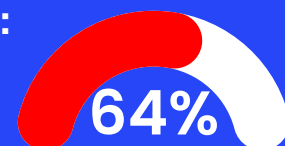
- Without action, this could increase existing disparities in health outcomes by race, ethnicity, income and geography.

Twenty states have recently passed legislation to expand coverage of comprehensive biomarker testing.



Of oncology providers reported that insurance coverage is a **significant or moderate barrier** to appropriate biomarker testing for their patients³

In HAWAII:



Of fully insured covered lives are enrolled in a plan with coverage that is more restrictive than National Comprehensive Cancer Network guidelines⁴

SUPPORTERS OF HAWAII BIOMARKER TESTING LEGISLATION HB 553 & SB 969



¹ Suehnholz SP, Nissan MH, Zhang H, et. al. Quantifying the Expanding Landscape of Clinical Actionability for Patients with Cancer. Cancer Discov. 2023.

² The Evolution of Biomarker Use in Clinical Trials for Cancer Treatments: Key Findings and Implications. Personalized Medicine Coalition, 2019.

³ ACS CAN. "Survey Findings Summary: Understanding Provider Utilization of Cancer Biomarker Testing Across Cancers." December 2021.

⁴ 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.

For more information please contact:

Cynthia Au, ACS CAN Hawaii Government Relations Director

✉ Cynthia.Au@cancer.org

☎ 808.460.6109



January 31, 2025

The Honorable Gregg Takayama, Chair
The Honorable Sue L. Keohokapu-Lee Loy, Vice Chair
House Committee on Health

Re: HB553- RELATING TO INSURANCE

Hawaii Medical Service Association (HMSA) appreciates the opportunity to provide comments on HB 553, which beginning 1/1/2026, requires health insurers, mutual benefit societies, health maintenance organizations, and health plans under the State's Medicaid managed care program to provide coverage for biomarker testing.

While the State Auditor's office provided an assessment on coverage for medically necessary biomarker testing (Auditor's Report No. 25-01), HB 553 seeks to mandate coverage for biomarker testing regardless of medical necessity. There already is a definition in statute for what is deemed medically necessary in Hawaii.

If the committee chooses to move this measure forward, we **request that the bill be amended to ensure that the mandated biomarker testing be for only those that are medically necessary.**

While these tests can save lives if the right test is performed, unproven tests can be both harmful and costly. As an example, Arizona recently legislated coverage for an unproven and fraudulent biomarker test. The mandate resulted in unnecessary appointments, unneeded medication, invasive diagnostic tests, and eventually a \$4.65 million consumer-fraud settlement.

We, along with other health plans, are constantly monitoring scientific evidence of clinical benefit and update our policies regularly based on new information.

As written, HB553 may require a new assessment report pursuant to Section 23-51 and 23-52 of the Hawaii Revised Statutes since it creates new mandated benefits which could increase costs for health plan members.

Thank you for the opportunity to provide comments on this measure.

Sincerely,

Dawn Kurisu
Assistant Vice President
Community and Government Relations



Biotechnology Innovation Organization
1201 New York Avenue, NW, Suite #1300
Washington, DC, 20005
202-962-9200

January 30, 2025

The Honorable Gregg Takayama
Chair, House Committee on Health
Hawai'i House of Representatives
415 S Beretania St.
Honolulu, HI 96813

Dear Representative Takayama and Members of the Committee:

The Biotechnology Innovation Organization (BIO) is pleased to support HB 553, which would require health plans to include coverage for biomarker testing, as specified. BIO supports timely, appropriate, and equitable access to biomarker testing as well as adequate coverage and reimbursement by public and private payers when backed by clinical guidelines or peer-reviewed scientific evidence. Delays in biomarker testing and coverage may lead to worse outcomes for patients.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, delay their onset, or prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers who have worked closely with stakeholders across the spectrum, including the public health and advocacy communities, to support policies that help ensure access to innovative and life- saving medicines and vaccines for all individuals.

Continuing advances in science and genomics are driving an increased understanding of human physiology and how diseases affect the body; these advances are helping researchers identify new biomarkers. As more biomarkers are identified, they have the potential to greatly enhance the drug development process by providing researchers with new ways to measure disease activity, reduce the amount of time required to show a medicine is safe or effective, and enable the development of more personalized, precision medicine—particularly where multiple biomarkers can inform the use of targeted drug combinations. Biomarkers can also allow researchers to better understand how effective a treatment is against a disease with endpoints that are difficult to define, providing clinicians with additional informative measurements in the early diagnosis of a disease and identifying differences in responses between individuals or subpopulations.

The development of personalized medicines that are more tailored to the individual patient using biomarkers helps drive efficiencies and improvements in patient care.

Biomarkers can help identify patients most likely to benefit from a specific treatment. For example, biomarkers are often used in cancer treatments to identify patients with tumors expressing certain genetic characteristics that indicate those patients are likely to respond to a

targeted cancer therapy. In another example, they can be used to ensure that a certain patient with a rare disease will most likely benefit from a specific therapy, particularly gene therapy.

Access to biomarker testing should not be delayed, as this may have detrimental effects on patient outcomes. If patients do not have access to biomarker testing, they will not know about life-saving targeted therapies that can improve their overall health outcome. Additionally, it is important that if access to a particular therapy is dependent upon specific biomarker, coverage and testing policies must immediately reflect the new advances in treatment. Coverage policies should never stand in the way of access to treatment.

The identification of biomarkers is not done through at home genetic DNA testing. It is done in a medical setting by healthcare professionals and clinicians within the scope of their license and experience to identify appropriate biomarkers for clinical trials. In addition, genetic counselors guide patients through proper clinical treatment guidelines and options. These health professionals must always have the ability to order all comprehensive biomarker testing panels necessary to ensure appropriate treatment and continuing care. Sadly, a February 2022 report by Milliman found that 48 states have no minimum coverage requirements for biomarker testing.¹

BIO supports the continual assessment of coverage requirements by public and private payers for novel biomarker testing that come to market. Additionally, public, and private payers should regularly review clinical guidelines, existing medical compendia, CMS coverage guidelines, recommendations of health professional organizations, and consensus statements to update their testing policies.

Biomarker testing should not be subject to lifetime limits. As disease stages progress over time and can vary from patient to patient, biomarker testing should be covered for all relevant panels of tests at any time in the continuum of care, if determined necessary by a health care professional.

For these reasons outlined above, we respectfully urge your YES vote on HB 553. If you have any questions, please do not hesitate to contact me to discuss this further.

Sincerely,



Brian Warren
Vice President, State Government Affairs

¹ Dieguez, G., Carioto, J., *The landscape of biomarker testing coverage in the United States*. (2022).

Members of the Committee on Health / Committee on Human Services & Homelessness

Conference Room 329 State Capitol

415 South Beretania Street

Honolulu, HI

January 30, 2025

RE: HB 553, Insurance Coverage for Biomarker Testing – SUPPORT

Chair Marten, Vice Chair Olds, and members of the committee:

On behalf of the approximately 815 Hawaiians living with chronic kidney disease, I'm writing to you to ask for your support for HB 553. This important bill would ensure that patients facing chronic diseases, such as kidney disease, are able to access and afford biomarker testing when necessary. Research shows that there are disparities in who is currently benefitting from biomarker testing. People of color and those in rural communities are less likely to be tested. Improving access to biomarker testing is key to reducing disparities in cancer outcomes and other serious health conditions, including kidney disease.

The American Kidney Fund (AKF) is the nation's leading nonprofit organization working on behalf of the 1 in 7 Americans living with kidney disease, and the millions more at risk, with an unmatched scope of programs that support people wherever they are in their fight against kidney disease, from prevention through transplant. With programs that address early detection, disease management, financial assistance, clinical research, innovation and advocacy, no kidney organization impacts more lives than AKF.

Biomarker testing is the analysis of a patient's tissue, blood or other biospecimen for the presence of a biomarker. Biomarker testing is an important step for accessing precision medicine, including targeted therapies that can lead to improved survivorship and better quality of life for cancer patients. Biomarker testing is increasingly important to cancer care, and for the treatment of other diseases including arthritis, other autoimmune conditions and rare diseases, including rare kidney diseases. Research into rare kidney

disease is progressing rapidly, and precision medicine has the potential to keep many people from ever developing end stage renal disease (ESRD), also known as kidney failure. While there are currently only two treatment options for those with ESRD (dialysis or kidney transplant), we are hopeful that other options may be available to patients in the future. As of now, neither dialysis nor transplant are inexpensive treatments, and both have a significant impact on a person's life and quality of life.

Unfortunately, kidney disease disproportionately affects people of color. One of AKF's top priorities is to advocate for health equity—and we believe that healthcare access and affordability are critical components. Without action to expand coverage of promising medical testing, such as biomarker testing, advances in precision medicine will likely lead to an increase in existing disparities in health outcomes. Every person deserves access to affordable biomarker testing.

HB 553 will increase access to biomarker testing – helping doctors to identify the right treatment at the right time. The bill aligns coverage of biomarker testing with the latest science, providing a gateway to targeted therapies that can lead to better health outcomes and improved quality of life. Biomarker testing could allow tens of thousands of patients to bypass costly and ineffective treatments by connecting patients with therapies that will be most effective for their individual disease.

Please support HB 553 to expand access to biomarker testing for all the citizens who could benefit.

Thank you for your consideration.

Sincerely,

Josie Gamez

Associate Director of State Policy and Advocacy

American Kidney Fund

Jgamez@kidneyfund.org

27 West Morten Avenue
Phoenix, AZ 85021-7246
phone (602) 618-0183 · fax (602) 926-8109
programs@askican.org · askican.org

3944 Pine Avenue
Long Beach, CA 90807
phone (562) 427-5561

ICAN Boards and Councils

Founding Chairman
Sidney M. Rosen, Esq.

Chairman, Board of Trustees
Sherry Weinstein

President and CEO
Marcia K. Horn, JD

*Chairman, Physicians Council and
Health Information Technology Council*
Robert H. Tamis, MD

Chairman, Board Governance
Carey Gregory

Chairman, Advisory Council
Cathy Dalzell

Honorary Chair, Board of Trustees
Cheryl J. Hintzen-Gaines

*Honorary Chairman, International
Corporate Advisory Council*
Robert T. Hanlon, PhD

Honorary Chair, International Board
Marc Mondavi

Co-Chairs, Golf Invitational
Wendy Look and Cathy Dalzell

Chairman, Texas Board of Advisors
Chuck Clayton

Chairman, Scientific Advisory Council
G. Robert Pettit, PhD

Chairman, Biomarkers Council
Scott M. Kahn, PhD

Health Equities Council
Andrew J. Brown, Jr., Director

Surgical Oncology Council
Björn Brücher, MD, FRCS, FACS, Chairman
Jeffrey M. Farma, MD

Medical Oncology Council
Wishwdeep Dhillon, MD
Michael S. Gordon, MD
Jeffrey D. Isaacs, MD
Shumei Kato, MD
Razelle Kurzrock, MD
John S. Link, MD
Robert A. Nagourney, MD
Sandip Patel, MD
Michael S. Roberts, MD
Shiva Singhal, MD

Radiology Council
Mitchell D. Achee, MD
and Gregory Goldstein, MD, Co-Chairmen

Interventional Radiology Council
Charles Nutting, DO and Fabio Komlos, MD,
Chairs

*Anatomic Pathology and
Molecular Diagnostics Council*
Anthony M. Magliocco, MD, Chairman
Arthur E. Sitelman, MD
Qingmei Xie, MD



January 30, 2025

The Honorable Gregg Takayama
Chair
Committee on Health
Hawai'i State Capitol
415 South Beretania Street
Honolulu, HI 96813

The Honorable Lisa Marten
Chair
Committee on Human Services and Homelessness
Hawai'i State Capitol
415 South Beretania Street
Honolulu, HI 96813

Re: HB 553, Relating to Insurance—Biomarker Testing

Dear Chair Takayama, Chair Marten, and Members of the House Committee on Health, and the House Committee on Human Services and Homelessness,

We are writing in strong support of HB 553 to require health insurers, mutual benefit societies, and health maintenance organizations to provide coverage for biomarker testing beginning on January 1, 2026. HB 553 will ensure that those Hawaiians covered by these plans will be covered for biomarker testing when medically appropriate.

The human impact is that more accurate testing sooner in the patient's journey both extends lives and saves many lives. The full fiscal impact must include two factors, a) the long-term fiscal impact of getting people on the right treatment sooner as this saves money for the health care system, including those systems managed by the state, and b) the economic impact of the regained productivity (and tax payments) of anyone who is or will be in the workforce. Extending lives, with a high quality of life, through better treatments, and saving lives through curing that patient—and both of these are

direct impacts of increased biomarker testing—means that Hawaii will have more tax revenues from a healthier workforce.

Founded in 1996, ICAN, International Cancer Advocacy Network, is a Phoenix-based non-profit that has helped over 19,000 Stage IV metastatic cancer patients in Hawai'i, throughout the United States, and in 82 countries. We work every day to secure the most effective drugs and treatments for our patients.

Our goal is to find the right drugs at the right time for each individual patient. Nothing is more critical in achieving that goal than testing for the ever-increasing number of actionable biomarkers identified in cancer. This testing allows the choice of the targeted drug most likely to reduce or eliminate that individual patient's specific cancer. Biomarker testing replaces educated guesswork with scientific evidence and makes truly personalized, precision medicine possible.

Stage IV metastatic cancer patients simply do not have the time to try any but the most optimal treatment options. Without the correct tests, delays in finding the right drugs at the right time lead to adverse consequences for the patient in terms of the cancer progressing to a more serious stage. This puts the patient in a weakened condition when and if the right drugs are finally found—thus making that therapy less effective.

The negative result for the healthcare system—a very avoidable negative result—is that the patient's care actually costs more overall: the costs of the wrong drugs initially, and then the higher costs for all the conditions that the patient suffers as a result of the inadequately treated and worsening disease.

For patients dealing with cancer, or other lethal or chronic diseases, finding “the right drug” for relief, treatment, or cure, can be a long struggle. The last thing that should happen is to make the patient (or an often overworked and overmatched oncology practice) fight with an insurance company to get the right test to know which drugs are most likely to work.

To delay the optimal treatment for any patient is wrong. To delay the optimal treatment for a Stage IV metastatic cancer patient is simply cruel beyond belief.

HB 553 ensures that the most vulnerable patients can quickly receive the treatments that biomarker tests indicate are most likely to be effective.

Codifying these critical patient protections into Hawaiian law is the right thing to do. Please let Stage IV metastatic cancer patients and their physicians fight cancer, not insurance companies.

Expanding coverage for biomarker testing will also help achieve other critical objectives of our health care system: reducing health disparities for the poor, for underserved ethnic or racial groups, and for residents of rural areas who lack access to comprehensive cancer centers.

On behalf of all the patients we serve in Hawaii who will be helped by HB 553, we thank you for your consideration of this very worthy legislation, and we look forward to seeing it successfully go through the legislative process and be signed into law.

That will be a day that all Hawaiians can celebrate.

Please do not hesitate to contact me at marcia@askican.org or (602) 513-9217 if you need any additional information. Thank you for your consideration.

Respectfully submitted,

Marcia K. Horn

Marcia K. Horn, JD
President and CEO
ICAN, International Cancer Advocacy Network
27 West Morten Avenue
Phoenix, AZ 85021-7246

(602) 618-0183
marcia@askican.org
<https://askican.org>

P. S. We realize there may be an effort to restrict biomarker testing to just cancer. Although ICAN is solely focused on helping cancer patients—specifically Stage IV cancer patients, the most serious stage—we strongly support biomarker testing for all diseases where it is medically appropriate.

Ask yourself this: if a loved one had a lethal or chronic disease, whether cancer or any other, wouldn't you want them to have access to the tests that can lead them to a better course of treatment and possibly be the difference in whether they survive?

If your answer is yes, then please ensure that the loved ones of others also have the ability to access biomarker testing for all diseases.



Hawaii State House Committee on Health and
House Committee on Human Services and Homelessness

HB553 RELATING TO INSURANCE

Good morning, Chair Takayama, Chair Marten and Members of the House Committee on Health and the House Committee on Human Services and Homelessness.

My name is Palani Smith, and I serve as the Regional Vice President for Hawaii and Guam of Liberty Dialysis. We are an affiliate of Fresenius Kidney Care.

Liberty Dialysis Hawaii stands in **STRONG SUPPORT** of HB553 Relating to Insurance. We hope that one day, Hawaii will be the nation's leader in using tools that help prevent kidney disease.

Kidney disease is a serious health issue in Hawaii. As of 2024, 5,749 Hawaii residents live with kidney failure, with 4,822 dependents on dialysis and 927 having received kidney transplants. High blood pressure (44%) and diabetes (29%) are the leading causes of kidney failure in our state. Persons of Native Hawaiian, Filipino, and Japanese ancestry are especially at-riskⁱ.

Biomarker testing is an essential tool in the fight against kidney disease. Kidney disease is a stealth disease, but testing for biomarkers makes it possible to effectively catch the disease in its very early stages far before dialysis or a transplant is needed. It helps assess kidney function (serum creatinine and estimated glomerular filtration rate), detects early kidney damage (urine albumin-to-creatinine ratio), and offers earlier and more precise detection of disease (neutrophil gelatinase-associated lipocalin and kidney injury molecule).

These biomarkers enable early and effective intervention to prevent kidney disease, significantly reducing complications, hospitalizations, and lowering healthcare costs and thereby increasing the quality of life for Hawaii's people and their families.ⁱⁱ

Liberty Dialysis Hawaii respectfully urges you to please pass HB553 and help Hawaii's people to have access to early diagnosis of kidney disease and improved health outcomes.

ⁱ Kidneyfund.org

ⁱⁱ Bmc.prg

**2025 Hawaii
Leadership Board**

**Testimony to the House Committee on Health Friday, January 31,
9:00 AM Hawaii State Capitol, Conference Room 329, and
Videoconference**

RE: House Bill No. 553 – RELATING TO INSURANCE

Travis Kikuchi, *Chair
Senior Vice President
Central Pacific Bank*

Lori McCarney, *Immediate
Past Chair Community
Advocate*

Tricia Medeiros, *Past Chair
Chief Operating Officer
The Plaza Assisted Living*

Gina Fujikami, *MD
The Queen's Medical
Center*

Kai Ohashi,
*Financial Advisor Edward
Jones*

Michael Robinson,
*Vice President Hawaii Pacific
Health*

Kimberly Soares, *Vice
President Atlas Insurance*

Gino Soquena,
*Executive Director
Hawaii Building and
Construction Trade Council*

Gordon Takaki, *Past
President Hawaii Island
Chamber of Commerce*

Cary Tanaka,
*Past President
Island Insurance
Companies*

Caroline Witherspoon,
*President Becker
Communications*

LJ R. Duenas,
*Executive Director
Alzheimer's Association*

Chair Takayama, Chair Marten, and Members of the Committees:

My name is Coby Chock, and I am testifying on behalf of the Alzheimer's Association Hawaii Chapter. We are in **strong support** of HB 553, which relates to insurance.

Currently, over 6 million Americans are living with Alzheimer's, yet nearly half remain undiagnosed. Early diagnosis is crucial as it opens doors to essential care and support services, enhances quality of life, and mitigates the financial burden of the disease. With the FDA's recent approval of treatments that slow Alzheimer's progression, early detection has become even more vital to maximize the benefits of these therapies.

Scientific advancements have brought us promising tools, such as a blood test for cognitive decline with a 90% accuracy rate. Despite these breakthroughs, the path to a dementia diagnosis is often lengthy and challenging, depriving families of valuable time. Presently, diagnosis depends heavily on observing cognitive decline, which means significant brain damage has already occurred by the time of diagnosis.

Researchers are diligently working to find straightforward and precise methods to detect Alzheimer's before severe symptoms manifest. Biomarkers, or biological indicators, are among the most promising avenues. Progress in biomarker research now allows us to observe Alzheimer's-related changes in the brain, monitor disease progression, and evaluate treatment efficacy.

However, the benefits of these scientific advancements are not fully realized due to limited accessibility. Insurance coverage for biomarker testing, including blood, saliva, and imaging tests, has not kept up with these innovations. The Alzheimer's Association is dedicated to removing these barriers to ensure that everyone affected by dementia can access these critical diagnostic tools.

Thank you for your attention and support. We urge you to back initiatives that expand access to biomarker testing, ultimately improving the lives of those impacted by Alzheimer's disease. Mahalo for the opportunity to testify in support! If you have questions, please contact me at 808-451-3410 or ckchock@alz.org

Coby Chock
Director of Public Policy and Advocacy
Alzheimer's Association - Hawaii

January 31, 2025

To: Chair Takayama, Chair Marten, Vice Chair Keohokapu-Lee Loy, Vice Chair Olds and Members of the House Committees on Health (HLT) and Human Services and Homelessness (HSH)

From: Hawaii Association of Health Plans Public Policy Committee

Date/Location: January 31, 2025; 9:00 a.m./Conference Room 329 & Videoconference

Re: Testimony with comments on HB 553 – Relating to Biomarker Testing

The Hawaii Association of Health Plans (HAHP) appreciates the opportunity to offer comments on HB 553. HAHP is a statewide partnership that unifies Hawaii's health plans to improve the health of Hawaii's communities together. A majority of Hawaii residents receive their health coverage through a plan associated with one of our organizations.

HAHP's member organizations recognize the significant benefits of biomarker testing in cancer treatment. However, we are concerned that the current bill lacks a medical necessity component. This omission could lead to the coverage of biomarker tests that are not clinically justified, resulting in increased healthcare costs that would ultimately be passed on to consumers. We urge you to consider this important aspect.

Thank you for your attention to this matter.

Sincerely,

HAHP Public Policy Committee
cc: HAHP Board Members



**Oncology Nursing
Society**

Support. Synergy. Strength.

January 30, 2025

Committee on Health
Committee on Human Services & Homelessness
Conference Room 329
State Capitol
415 South Beretania Street
Honolulu, HI 96813

Dear Chairpersons Takayama and Marten, Vice Chairpersons Loy and Olds, and Members of the Committees on Health, and Human Services and Homelessness:

On behalf of the Oncology Nursing Society (ONS) and the 218 oncology nurse members in the state of Hawaii, I am writing to express our strong support for **HB553**, which requires insurance coverage for biomarker testing. We believe that this legislation is critical in ensuring that oncology patients receive the most effective and personalized treatments available.

ONS is a professional association that represents the over 100,000 oncology nurses in the United States and is the professional home to more than 35,000 members. ONS is committed to promoting excellence in oncology nursing and the transformation of cancer care. Since 1975, ONS has provided a professional community for oncology nurses, developed evidence-based education programs and treatment information, and advocated for patient care, all in an effort to improve the quality of life and outcomes for patients with cancer and their families.

A biomarker is a biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease. It may be used to see how well the body responds to a treatment for a disease or condition.

Biomarker testing is a significant advancement in cancer care and plays a vital role in modern oncology by helping identify the specific characteristics of an individual's cancer. Personalized treatment plans based on biomarker results allow oncologists to match patients with the most effective therapies for their unique cancer profile. This targeted approach not only improves treatment outcomes but also minimizes unnecessary side effects associated with ineffective treatments.

Research consistently demonstrates the positive impact of biomarker utilization on patient care. Studies have shown that patients receiving targeted therapies based on biomarker testing have improved progression-free survival rates and quality of life compared to those receiving conventional treatments. Additionally, as cancer treatment continues to evolve, the importance of access to



**Oncology Nursing
Society**

Support. Synergy. Strength.

biomarker testing becomes increasingly significant in navigating the rapidly changing landscape of oncological care.

Providing coverage for biomarker testing fosters equity in access to the latest advancements in cancer treatment. It ensures that patients, regardless of their financial situation, can benefit from critical testing that can inform their treatment decisions. Furthermore, by supporting a wider range of treatment options, this legislation empowers the oncology community to provide tailored care, giving them the tools necessary to make informed clinical decisions.

In conclusion, **HB553**, represents a significant step forward in creating a more equitable and effective oncology treatment environment in Hawaii. We strongly urge the committee to support this legislation to ensure that all cancer patients have access to the biomarker testing necessary for their care.

Thank you for your attention to this important matter. Should you require any further information or wish to discuss our support, please feel free to contact healthpolicy@ons.org

Sincerely,

The Oncology Nursing Society (ONS)



1301 Pennsylvania Avenue,
NW
Suite 400
Washington, D.C. 20004
P :: 202.783.8700
F :: 202.783.8750
W:: AdvaMed.org

January 30, 2025

Honorable Lisa Marten
Chair, Committee on Human Services and Homelessness
Honorable Gregg Takayama
Chair, Committee on Health
Hawai'i House of Representatives
415 South Beretania St
Honolulu, HI 96813

RE: HB 553 – Support

Dear Chair Marten and Chair Takayama:

On behalf of AdvaMed, the MedTech Association, I am writing in support of HB 553, legislation that will improve patient outcomes by ensuring access to vital biomarker testing.

AdvaMed is the world's largest association representing the full spectrum of medical technology innovators and manufacturers. AdvaMedDx, a division of AdvaMed, represents over 80 manufacturers of *in vitro* diagnostic (IVDs) tests and technologies. Our member companies produce advanced IVD tests and technologies that allow early detection of disease, facilitate evidence-based medicine, improve patient and public health, and enable precision medicine. AdvaMedDx is the only advocacy organization exclusively addressing policy issues facing diagnostic manufacturers in the United States and abroad.

The significance of biomarker testing in patient care cannot be overstated. It is a game-changer in tailoring patient management and prevention plans by integrating individual medical histories and clinical symptoms. This approach is instrumental not just in cancer treatment but also across various medical fields like cardiology, neurology, infectious diseases, and autoimmune disorders. Conditions such as Alzheimer's Disease, Rheumatoid Arthritis, and Preeclampsia are just a few examples where biomarker testing can make a substantial difference.

Unfortunately, current health care coverage for biomarker testing is failing to keep pace with scientific advancements. HB 553 aims to bridge this gap by requiring state-regulated health care plans to cover comprehensive biomarker testing when supported by medical and scientific evidence, including nationally recognized clinical practice guidelines. Timely access to



appropriate biomarker testing will result in better health outcomes, advance health equity, and reduce costs. For these reasons, AdvaMed strongly supports HB 553.

Your support can transform the landscape of patient care, and we look forward to your leadership in this critical healthcare initiative.

Sincerely,

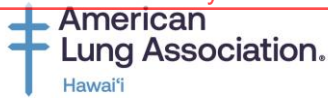


Zach Rothstein
Executive Director
AdvaMedDx



Darbi Gottlieb
Director, State Government and Regional Affairs
Advanced Medical Technology Association (AdvaMed)





COMMITTEE ON HEALTH
Rep. Gregg Takayama, Chair
Rep. Sue L. Keohokapu-Loy, Vice Chair

Friday, January 31, 2025
9:15 AM – Room 329

Testimony In Support of House Bill 553 Relating to Insurance

The American Lung Association in Hawai'i urges lawmakers to support House Bill 553 to increase coverage of biomarker testing. This legislation will improve access to critical cancer care for patients in Hawai'i, including those with lung cancer.

The American Lung Association is the oldest voluntary public health association in the United States, currently representing the more than 35 million Americans living with lung diseases, including the nearly 800 people who get diagnosed with lung cancer each year in Hawai'i. The Lung Association is the leading organization working to save lives by improving lung health and preventing lung disease through research, education and advocacy.

Comprehensive biomarker testing allows doctors to identify abnormalities in a cell's DNA, which in turn helps healthcare providers determine the best course of treatment for cancer patients. This is particularly important when treating lung cancer, as there are currently FDA-approved lung cancer treatments for tumor abnormalities in at least nine distinct genes.ⁱ Studies show that individuals with lung cancer who have access to biomarker testing and are thus able to receive targeted therapy treatments have better overall chances of survival.ⁱⁱ Biomarker testing is a crucial part of both cancer care and treatment of other chronic conditions and has been incorporated into many clinical guidelines so that doctors may make the best decisions for their patients' health.

Despite the evidence for the value of biomarker testing, many health coverage plans have been found to be more restrictive than the National Comprehensive Cancer Network's guidelines for biomarker testing.ⁱⁱⁱ Many patients who should receive biomarker testing may be unable to do so because of insurance coverage restrictions and high out-of-pocket costs. Therefore, it is important that this legislation increases coverage of biomarker testing and removes some of these barriers to care.

We have an opportunity to increase equitable access to healthcare by passing this bill. Current biomarker testing rates show significant racial disparities. For example, research shows that people of color with non-small cell lung cancer are less likely to receive testing than white patients.^{iv}

It is imperative that this legislation include coverage for biomarker testing outside of oncology. Treatment for many chronic diseases may also rely on biomarker testing, such as rheumatoid arthritis, diabetes, and certain rare diseases. The Lung Association urges lawmakers to keep the scope of the legislation broad so that patients in Hawai'i receive the best care that they can.

Increasing coverage of biomarker testing will improve health equity in and make cancer and chronic disease care more affordable and more accessible for patients. The American Lung Association in urges you to support House Bill 553.

Pedro Haro
Executive Director
American Lung Association in Hawai'i
pedro.haro@lung.org

ⁱ [Lung Cancer Biomarker Testing | American Lung Association](#)

ⁱⁱ [Value of Precision Medicine in Advanced Non-Small Cell Lung Cancer: Real-World Outcomes Associated with the Use of Companion Diagnostics - PubMed \(nih.gov\); The Effect of Advances in Lung-Cancer Treatment on Population Mortality - PubMed \(nih.gov\)](#)

ⁱⁱⁱ [Alignment of health plan coverage policies for somatic multigene panel testing with clinical guidelines in select solid tumors \(futuremedicine.com\)](#)

^{iv} Presley CJ, PR, Chiang AC, Longtine JA, Adelson KB, Herbst RS, Nussbaum NC, Sorg R, Abernethy AP, Agarwala V, and Gross CP. Disparities in next generation sequencing in a population-based community cohort of patients with advanced non-small cell lung cancer. *Journal of Clinical Oncology* 2017 35:15_suppl, 6563-6563.

HB-553

Submitted on: 1/28/2025 7:14:41 PM

Testimony for HLT on 1/31/2025 9:00:00 AM

Submitted By	Organization	Testifier Position	Testify
Josh Fowler	Individual	Support	Written Testimony Only

Comments:

SUPPORT

RE: Strong Support of HB553 – RELATING TO INSURANCE, MANDATORY HEALTH INSURANCE COVERAGE FOR BIOMARKER TESTING

Written Testimony

My name is Joshua Fowler, and I am a volunteer and advocate with the American Cancer Society - Cancer Action Network. I am writing to express my strong support for HB553, which mandates health insurance coverage for biomarker testing starting January 1, 2026.

Why This Matters:

- **Improving Outcomes:** States like California and Illinois have already implemented similar mandates, allowing patients quicker access to targeted therapies that improve survival rates and quality of life.
- **Reducing Inequities:** Without mandated coverage, only those who can afford it out-of-pocket can benefit. We must ensure all residents, regardless of economic status, have access to this life-saving tool.
- **Healthcare Efficiency:** Biomarker testing can reduce overall healthcare costs by avoiding ineffective treatments and focusing resources on therapies that work for an individual's specific condition.

Looking at Other States:

- **Better Practices:** States like California have seen improved cancer outcomes with mandated biomarker testing coverage, showing Hawaii can benefit similarly.
- **Room for Improvement:** States without this coverage force patients into prolonged and less effective treatment paths, increasing suffering and costs—Hawaii should lead in patient-centered care.

Thank you for the opportunity to testify. I urge the committee to support HB553 and ensure equitable access to biomarker testing for all Hawaii residents.

With gratitude,
Joshua Fowler
Honolulu, Hawaii

HB-553

Submitted on: 1/29/2025 9:32:53 AM

Testimony for HLT on 1/31/2025 9:00:00 AM

Submitted By	Organization	Testifier Position	Testify
Cheryl K. Okuma	Individual	Support	Written Testimony Only

Comments:

My name is Cheryl K. Okuma and I am an advocate for the American Cancer Society Cancer Action Network. I am in **STRONG SUPPORT** of HB553.

I am a breast cancer survivor. In my immediate family of five (5), two others have endured other forms of cancer (prostate, colon). On my paternal side, my aunt is also a breast cancer survivor—twice. This causes me to wonder whether genetics is a factor. When I fill out forms for my check ups and exams I am asked if other immediate family members and those on my paternal and maternal side have had cancer, and what type.

Biomarker testing would provide a better way to determine what factors are involved, and in turn lead to the best treatment for cancer patients. Access to biomarker testing will lead to better health outcomes for cancer patients.

Progress in improving cancer outcomes increasingly involves the use of precision medicine, using information of a person's genes, proteins or other substances to diagnose and treat cancer in a targeted way. Biomarker testing is a personalized, important step to accessing precision medicine and therapies, but insurance coverage is failing to keep pace.

Biomarker testing will lead to improved survivorship and better quality of life for cancer patients. Nearly 60% of all cancer drugs approved in the last 5 years require or recommend biomarker testing before use.

Sincerely,

Cheryl K. Okuma

Wailuku, 96793

HB-553

Submitted on: 1/29/2025 1:24:33 PM

Testimony for HLT on 1/31/2025 9:00:00 AM

Submitted By	Organization	Testifier Position	Testify
Cynthia J. Goto	Individual	Support	Written Testimony Only

Comments:

Support

RE: Strong Support of HB553 – Relating to Insurance
Friday, January 31, 2025; TIME: 9:00AM
Committee on Health / Committee on Human Services & Homelessness

Chair Takayama, Chair Marten and joint committee members:

My name is Natalie Hyman and I am a patient advocate living with Stage IV metastatic breast cancer. I am in STRONG SUPPORT of HB553.

I was diagnosed with stage IV metastatic breast cancer in 2020 and am still here today thanks in part to biomarker testing. At the time of my initial diagnosis, my oncologist ordered biomarker testing of my tumor. This tumor testing was the professional standard of care in breast cancer oncology. This is probably why my local oncologist ordered this test without expressing any concerns to me about possible insurance denial. The results of this test would reveal if any targeted therapies might work on my cancer.

My insurer denied coverage for this test based on their determination of medical necessity. The company's reason for denying me coverage for this standard of care biomarker testing was: "The use of comprehensive genomic profiling (expanded cancer mutation panels) for selecting targeting cancer treatment does not meet payment determination criteria because there is a lack of evidence that this technique improves health outcomes.

Many patients give up upon initial insurance denial because they do not have the energy or knowledge to appeal it. In my case, the testing company agreed to appeal on my behalf with help from my oncologist. Despite their months-long efforts, the insurer still refused to pay for this test. The cost was \$5,800. This biomarker test arguably meets the definition of medical necessity under current Hawaii law.

Medically necessary - as decided by the insurance plan's medical director – is often inconsistent with the recommendations of the treating physician, professional standards of care, and clinical practice guidelines.

Another example of my insurer denying coverage for a medically necessary biomarker test happened to me in 2023. In July 2023, my cancer progressed, which meant I needed to change treatments. Earlier that year (January 27, 2023), the FDA approved elacestrant for ESR1-mutated metastatic breast cancer with disease progression following at least one line of endocrine therapy. The FDA also approved a companion diagnostic device (a specific biomarker test) to identify patients with breast cancer for treatment with elacestrant. My cancer subtype and treatment history aligned with this newly approved drug; therefore, my oncologist ordered the corresponding test. It revealed that I did have the ESR1 mutation, and I was approved to receive elacestrant treatment. However, my insurer did not approve coverage for this biomarker test. Now it has been over 18 months and the insurer still has not issued a coverage decision. This test costs \$9,650. **This biomarker testing upon my cancer progression fit within the Hawaii statutory definition of "medical necessity" and yet the insurer will not pay for it. This test was FDA approved and directly impacted my ability to use a new drug – that may be my best chance**

against cancer. Moreover, ESR1 biomarker testing is specifically recommended in the NCCN Guidelines for breast cancer.

Hawaii's statutory definition of "medical necessity" depends upon the insurance company's medical director agreeing that the requested health intervention is indeed medically necessary. This puts the insurance company's interests above patient health outcomes. Current Hawaii law allows insurance companies to deny coverage by using the ambiguous and subjective definition of "medical necessity."

Patients should be able to get biomarker testing when it is ordered by their doctor and there is sufficient evidence that it can help guide their treatment. But that's not what's happening today. As my experience and others show, currently insurers in our state can use their own determinations of medical necessity to limit access to proven and necessary testing. In order to help future patients avoid the stress and struggle that I've experienced, I urge you to support HB553.

With thanks,

Natalie Hyman
Kailua, Hawaii 96734

Lynda Asato
1255 Nuuanu Avenue #1714
Honolulu, HI 96817
808-342-1850

RE: Strong Support of HB 553 – Relating to Insurance

Friday, January 31, 2025; TIME: 9:00AM

Committee on Health / Committee on Human Services & Homelessness

Chair Takayama, Chair Marten and joint committee members:

My name is Lynda and I am an advocate for the American Cancer Society Cancer Action Network. I am in STRONG SUPPORT of HB553.

I am a thirty-year survivor of cancer. I had to pay for my own genetic testing for Breast Cancer in 1993 and again in 2017. The cost was about \$3,000 each time. Insurance did not pay for the testing. Through the tests, I found out that I am not among those with BRCA genetic disorders. I am PALB2 and have that genetic mutation. The knowledge helps me to make better decisions about my health.

I am hoping that my insurance will pay for biomarker testing when I need it, should my cancer recur. I'm older and have been through three bouts of cancer, which makes me at higher risk of recurrence. I'm also retired so not able to readily pay for higher cost testing, as well as treatments, when medically necessary, which will require biomarker testing to qualify for now and in the future.

For these reasons, I'm a strong supporter of HB 553. Thank you for accepting my testimony.

Mahalo,

Lynda Asato
1255 Nuuanu Avenue #1714
Honolulu, HI 96817
808-342-1850

RE: Strong Support of HB 553 – Relating to Insurance
Friday, January 31, 2025; TIME: 9:00AM
Committee on Health / Committee on Human Services & Homelessness

Chair Takayama, Chair Marten and joint committee members:

Our names are Susan and Peter Hirano. We submit this testimony in STRONG SUPPORT of HB553.

In October 2021 Susan was diagnosed with Stage 4 breast cancer. The diagnosis rocked our world and set us on a journey that continues on today.

We recall our oncologist, Dr. Clayton Chong (who has since passed away), talking with us very early in this journey about doing a “biomarker test” on Susan’s biopsy. This test (by Guardant Health) as he explained it, would help us identify what path we can take for treatment.

It never occurred to us that this test would not be considered “medically necessary” and would not be covered by our insurance plan. After all, the test was ordered by a trusted oncologist with years of experience.

We were shocked to see this claim denied along with a \$9,650 bill. The explanation of benefits from the insurance company read: “This claim was reviewed by our medical staff. The information we have in your case does not meet the medical criteria for payment.”

We appealed the denial and the claim was ultimately approved for partial payment. However, the thought that an insurance company could deem this test “unnecessary” makes no sense. To add to that, in the stage of Susan’s cancer journey we were in, we were emotionally fragile state trying to absorb and accept this unexpected turn in our lives - and having to expend energy with an insurance company to appeal a claim for a necessary test is frustrating beyond measure.

One final note.

Over the last 3+ years in this cancer journey we have come to understand that there are amazing medical advances to treat different types of cancer. MANY of these treatments are targeted therapies engineered specifically for certain mutations. These mutations are not known without biomarker testing.

Without biomarker testing, these therapies may never be identified for use by patients like Susan. These new therapies have the potential to provide cancer patients a higher quality of life; a longer life; and maybe some day a cure.

Thank you for the opportunity to provide our story.

Respectfully,

Peter and Susan Hirano
Honolulu

Beverly Wong
Honolulu, Hawaii 96818

RE: Strong Support of HB 553 – Relating to Insurance

Friday, January 31, 2025; TIME: 9:00AM

Committee on Health / Committee on Human Services & Homelessness

Chair Takayama, Chair Marten and joint committee members:

I am Beverly Wong, an advocate of the American Cancer Society, Cancer Action Network, and strongly support HB553: Relating to Insurance.

Due to the years of successful cancer research, my son was cured from his Acute Leukemia/Lymphomia and it is now in remission.

I beg you to pass this very important bill which will save many lives in the future and bring happiness to so many more families.

With thanks,

Beverly Wong
Honolulu, Hawaii 96818

HB-553

Submitted on: 1/30/2025 9:49:55 AM

Testimony for HLT on 1/31/2025 9:00:00 AM

Submitted By	Organization	Testifier Position	Testify
Tina Wildberger	Individual	Support	Written Testimony Only

Comments:

Aloha Chair, Vice-Chair & Members,

In strong support for TIMELY biomarker testing:

Don't let our profit-driven medical insurance industry continue to delay, deny and drag out approval for the most appropriate care for struggling patients. 20 other states have already passed legislation to expand biomarker testing. The for-profit medical insurance industry isn't keeping up with medical advancements that can save money and lives.

Targeted therapies that lead to improved survivorship need biomarker testing. It is an important step to accessing precision medicines. This measure removes barriers so doctors and patients can make the best decisions for care. Thank you for your consideration and passing this measure.

HB-553

Submitted on: 1/31/2025 7:58:30 AM

Testimony for HLT on 1/31/2025 9:00:00 AM

Submitted By	Organization	Testifier Position	Testify
Jennifer Hausler	Individual	Support	Written Testimony Only

Comments:

RE: Strong Support of HB 556: Relating to Colorectal Cancer

Friday, January 31, 2025; TIME: 9:00AM

Committee on Health / Committee on Human Services & Homelessness

Chair Takayama, Chair Marten and joint committee members:

My name is Jennifer Hausler and I am an advocate for the American Cancer Society Cancer Action Network.. I am in STRONG SUPPORT of HB556.

After losing two husbands, a sister and many relatives and classmates to cancer, I know biomarker testing is a key to achieve beter health outcomes and can save lives. Over 17 States have passed laws to make it part of the standard of care and include insurance coverage. Hawaii should join the other States.

Sincerely,

Jennifer Ikeda Hausler

GO GO(VS

Pearl City, Hawaii 96782