



Alone we are rare. Together we are strong.®

February 7, 2024

The Honorable Scot Matayoshi, Chair
House Committee on Consumer Protection &
Commerce
Hawai'i State Capitol, Room 422
415 South Beretania St.
Honolulu, HI 96813

The Honorable Cory Chun, Vice Chair
House Committee on Consumer Protection &
Commerce
Hawai'i State Capitol, Room 406
415 South Beretania St.
Honolulu, HI 96813

Re: Support for House Bill 553 – Coverage for Biomarker Testing

Dear Chair Matayoshi, Vice Chair Chun, and Members of the Committee on Consumer Protection & Commerce;

On behalf of the more than 30 million Americans living with one of the over 10,000 known rare diseases, the National Organization for Rare Disorders (NORD) writes to share our support for House Bill 553 (HB553), legislation that would require access to biomarker testing. However, it is vital that HB553 is not limited to one disease area in order for the legislation to fully benefit our community. We encourage you to support this legislation without any amendments that would limit its use to any one particular disease group.

NORD is a unique federation of non-profits and health organizations dedicated to improving the health and well-being of people living with rare diseases. NORD was founded over 40 years ago, after the passage of the Orphan Drug Act (ODA), to formalize the coalition of patient advocacy groups that were instrumental in passing that landmark law. NORD's mission has always been, and continues to be, to improve the health and well-being of people with rare diseases by driving advances in care, research, and policy. We believe that all patients should have access to quality, accessible, innovative, and affordable health coverage that is best suited to their medical needs.

Biomarkers are characteristics, such as radiographic abnormalities or biological molecules found in blood, tissue, or other bodily fluid that can be objectively measured to determine the sign of a condition or disease. The result of a biomarker test can be used to assess how well a patient responds to a treatment for a disease or condition, as well as determine the best course of action for a patient.¹ This can significantly improve patient outcomes; for instance, in rare cancers, including pediatric cancers, this can mean that treatments can be targeted specifically for the

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genetic or molecular makeup of the tumor.ⁱⁱ Biomarker testing allows for targeted care and precision medicine, thus decreasing the treatment time and increasing the likelihood of survivorship for patients.ⁱⁱⁱ While currently biomarker testing is often used in oncology, biomarker testing can benefit patients in many disease groups, including autoimmune diseases, and research is underway that may unlock benefits in other rare conditions. **This is why it is essential that HB553 remain disease agnostic.**

Unfortunately, patient access to biomarker testing is often delayed or denied by health insurance plans. HB553 would require coverage for biomarker testing if the use of the test is supported by medical and scientific evidence. Furthermore, it would establish clear parameters and processes for utilization review, including prior authorization, to ensure limited disruptions in care for patients.

We urge you to support this legislation to ensure all patients can benefit from this quickly evolving aspect of precision medicine by swiftly passing HB553 out of the House Consumer Protection and Commerce Committee. Thank you for your attention to this matter. For any questions, please contact me at lviscarra@rarediseases.org.

Sincerely,



Lindsey Viscarra
State Policy Manager
National Organization for Rare Disorders

ⁱ Biomarkers. ONS. (n.d.). Retrieved December 7, 2022, from <https://www.ons.org/genomics-taxonomy/biomarkers>

ⁱⁱ Biomarker testing for cancer treatment. National Cancer Institute. (n.d.). Retrieved December 7, 2022, from <https://www.cancer.gov/about-cancer/treatment/types/biomarker-testing-cancer-treatment#:~:text=Biomarker%20testing%20is%20a%20way,how%20certain%20cancer%20treatments%20work>.

ⁱⁱⁱ Biomarker testing for cancer treatment. National Cancer Institute. (n.d.). Retrieved December 7, 2022, from <https://www.cancer.gov/about-cancer/treatment/types/biomarker-testing-cancer-treatment#:~:text=Biomarker%20testing%20is%20a%20way,how%20certain%20cancer%20treatments%20work>.