DISABILITY AND COMMUNICATION ACCESS BOARD

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April 2, 2024

TESTIMONY TO THE HOUSE COMMITTEE ON CONSUMER PROTECTION AND COMMERCE

House Concurrent Resolution 53 – Requesting the Auditor to Assess the Social and Financial Effects of Mandatory Health Insurance Coverage for Biomarker Testing

The Disability and Communication Access Board (DCAB) supports House Concurrent Resolution 53 – Requesting the Auditor to Assess the Social and Financial Effects of Mandatory Health Insurance Coverage for Biomarker Testing.

Biomarker testing is an important diagnostic tool that may lead to early detection of many diseases. If insurance plans do not provide coverage, many people will not be able to afford the testing.

Thank you for considering our position.

Respectfully submitted,

KIRBY L. SHAW
Executive Director

ALZHEIMER'S ASSOCIATION®

Testimony to the House Committee on Human Services
Tuesday, April 2, 2024; 2:00 p.m.
Hawaii State Capitol, Conference Room 329, and Videoconference

RE: HOUSE CONCURRENT RESOLUTION 53 – REQUESTING THE AUDITOR TO ASSESS THE SOCIAL AND FINANCIAL EFFECTS OF MANDATORY HEALTH INSURANCE COVERAGE FOR BIOMARKER TESTING.

Chair Mark Nakashima, Vice Chair Jackson Sayama, and Members of the Committee:

The Alzheimer's Association–Aloha Chapter serves the residents of Hawaii to help all those facing Alzheimer's disease and other dementias by providing local support groups and educational resources while advancing crucial research and public policy initiatives. We testify in **SUPPORT of HOUSE CONCURRENT RESOLUTION NO. 53.**

Alzheimer's disease is a public health crisis across the country. In Hawaii, approximately 29,000 individuals aged sixty-five and older live with Alzheimer's disease. This figure is projected to increase to over 35,000 by next year. In addition, many are experiencing subjective cognitive decline — one of the earliest warning signs of future dementia. In 2020, 6.7% of individuals aged 45 and over reported increased confusion or worsening memory loss, putting them at risk of later developing dementia.

This resolution, as received by your Committee, would request that the State Auditor assess, in accordance with sections 23-51 and 23-52, Hawaii Revised Statutes, the social and financial effects of mandating health insurance coverage for medically necessary biomarker testing for diagnosis, treatment, appropriate management, or ongoing monitoring of a person's disease or condition to guide treatment decisions when supported by medical and scientific evidence, as provided in House Bill No. 2223, House Draft No. 1, Regular Session of 2024, and to submit a report of its findings and recommendations, including any proposed legislation, to the Legislature no later than twenty days before the convening of the Regular Session of 2025.

An early and accurate diagnosis of Alzheimer's can improve access to care and support services, enhance quality of life, and reduce the financial impact of the disease. With the historic approval of treatments that slow the progression of the disease, early detection and diagnosis of Alzheimer's are even more critical to ensure individuals receive the most benefit at the earliest point possible in the disease progression.

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Current diagnosis of Alzheimer's disease relies largely on documenting cognitive decline, at which point Alzheimer's has already caused severe brain damage. Experts believe that biomarkers (short for "biological markers") offer one of the most promising paths to improve dementia detection, diagnosis, and treatment.

Currently, there are some FDA-approved biomarker tools that, when applicable, can aid in diagnosing people with symptoms of Alzheimer's or other dementia (e.g., brain imaging). Some of these tools have a wealth of research and clinical data to support their use in a clinical setting (e.g., biomarkers in cerebrospinal fluid (CSF)), while other emerging biomarkers are promising but still under investigation (e.g., blood tests and genetic risk profiling). Continued progress around blood-based amyloid biomarker markers will likely lead to new diagnostic tools coming to market within the next few years. Insurance coverage for biomarker testing (including blood tests, saliva tests, imaging, etc.) is currently not keeping up with scientific discoveries and treatment progress. Existing healthcare disparities and challenges to obtaining a dementia diagnosis may be exacerbated if new biomarker testing opportunities cannot be accessed.

Without acting on this legislation, dementia diagnoses may take up to two years, increasing the long-term costs to the individual, family, and the state. Because diagnosis leads to lower costs of care for people living with dementia, access to biomarker testing can accelerate these cost savings. In a 2018 analysis, diagnosis led to projected cost savings of approximately $63,000, of which $30,000 was in Medicare savings, $20,000 in Medicaid savings, and $13,000 in other savings. (2018 Alzheimer's Facts and Figures)

The Alzheimer's Association requests your favorable consideration of this measure based on an earlier and faster diagnosis that offers individuals and families more time with their loved ones. **We ask you to pass House Concurrent Resolution 53.**

Mahalo for the opportunity to testify. If you have questions, please contact Ron Shimabuku at 808.451.3410 or rkshimabuku@alz.org.

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House Committee on Consumer Protection and Commerce
Representative Mark Nakashima, Chair
Representative Jackson Sayama, Vice Chair

Hearing Date: Tuesday, April 2, 2024

ACS CAN in STRONG SUPPORT of HCR 53 – REQUESTING THE AUDITOR TO ASSESS THE SOCIAL AND FINANCIAL EFFECTS OF MANDATORY HEALTH INSURANCE COVERAGE FOR BIOMARKER TESTING.

Cynthia Au, Government Relations Director – Hawaii Guam
American Cancer Society Cancer Action Network

Thank you for the opportunity to be in **STRONG SUPPORT** of HCR 53. This resolution requests the State Auditor assess, in accordance with sections 23-51 and 23-52, Hawaii Revised Statutes, the social and financial effects of mandating health insurance coverage for medically necessary biomarker testing for diagnosis, treatment, appropriate management, or ongoing monitoring of a person's disease or condition to guide treatment decisions when supported by medical and scientific evidence, as provided in House Bill No. 2223, House Draft No. 1, Regular Session of 2024, and to submit a report of its findings and recommendations, including any proposed legislation, to the Legislature no later than twenty days before the convening of the Regular Session of 2025.

The American Cancer Society Cancer Action Network (ACS CAN), the nonprofit, non-partisan advocacy affiliate of the American Cancer Society advocates for public policies to reduce the cancer burden for everyone. On behalf of our constituents, many of whom have been personally affected by cancer, we urge your support of this important bill.

This resolution will move the state forward in improving patient access to care. Biomarker testing is the analysis of a patient's tissue, blood, or biospecimen for the presence of a biomarker, to identify mutations that may impact treatment decisions. 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 and reduced costs. Comprehensive biomarker testing allows patients to avoid treatments that are likely to be ineffective. 60% of oncology drugs launched in the past five years require or recommend biomarker testing prior to use.

Currently, of the Hawaii policies that were reviewed in a recent peer reviewed study, 64% were classified as "more restrictive" than National Comprehensive Cancer Network guidelines for biomarker testing for advanced breast, non-small cell lung cancer, melanoma and/or prostate cancer – common cancers for which there are many effective targeted treatments available.

As precision medicine becomes the standard of care in treatment for diseases like cancer, mental health, and autoimmune diseases, biomarker testing has risen in importance as the gateway to many of these therapies. Attached to this testimony is a fact sheet showing the support of patient and provider organizations. This bill will impact more than cancer patients. Patients with lupus, ALS, preeclampsia, or arthritis benefit from biomarker testing. There is groundbreaking research in biomarker testing for Alzheimer's and heart disease. This legislation is about making sure current patients and future patients can access the testing needed to find treatment best suited for them.

According to a fiscal analysis conducted on biomarker testing coverage, the average allowed unit cost to insurers, per biomarker test, ranges from only $78 to $224. However, when biomarker testing is not covered by insurance, patients can be on the hook for hundreds or even thousands of dollars in out-of-pocket costs.

Legislation has been enacted in 16 states and is currently being heard in 12 others. We urge the committee to request the State Auditor to study biomarker testing impact in the state to make it possible for Hawaii patients to get the right treatment, at the right time.

Thank you again for the opportunity to provide testimony in SUPPORT on this important matter. Should you have any questions, please do not hesitate to contact Government Relations Director Cynthia Au at 808.460.6109, or Cynthia.Au@Cancer.org.

Biomarker Testing and Cost Savings

Timely access to guideline-indicated comprehensive biomarker testing can help achieve the triple aim of health care including better health outcomes, improved quality of life, and reduced costs. Comprehensive biomarker testing looks for all recommended biomarkers based on clinical guidelines. This testing can lead to treatments with fewer side effects, longer survival and allow patients to avoid treatments that are likely to be ineffective or unnecessary. Exposure to these ineffective treatments can exacerbate the physical, emotional, and economic burdens of disease.

Spending on Biomarker Testing Can Yield Savings on Treatment Costs

There are several studies looking at the cost effectiveness of *single marker testing*, which are most likely to be covered by insurance plans currently, to more comprehensive testing, which isn't always covered. Comprehensive biomarker testing is often done with a *panel test* that assesses multiple biomarkers (e.g., genes or proteins) in one test as compared to single marker testing that assesses one marker per test. For many patients, panel testing is most appropriate. Examples include when there is limited tissue available for testing or as recommended by clinical practice guidelines to gain sufficient information to appropriately guide treatment decisions.

Often paying more upfront for comprehensive testing can result in overall savings in treatment costs.

- In a study sponsored by CVS Health looking at total cost of care for non-small cell lung cancer patients who received broad panel biomarker testing in comparison to narrow panel biomarker testing; broad panel testing had an average additional up-front cost increase of approximately $1,200 in comparison to narrow panel biomarker testing. However, those patients who underwent broad panel biomarker testing experienced a savings of approximately $8,500 per member per month in total cost of care, as a result of more optimal treatment.[i]
- Other studies have found upfront broader biomarker testing results in substantial cost savings for commercial payers ($3,809; $127,402; and $250,842 less than exclusionary, sequential testing, and hotspot panels, respectively)[ii] and decreased expected testing procedure costs to the health plan by $24,651.[iii]
- Some studies have found minimal cost increases as a result of the costs of more effective treatment and prolonged patient survival.[iv, v]

Costs to Insurers

According to a 2022 analysis of biomarker testing coverage by Milliman, the average allowed unit cost to insurers per biomarker test ranges from $78.71 (Medicaid) to $224.40 (large group self-insured).[vi] When biomarker testing is not covered by insurance, patients can be on the hook for hundreds or even thousands of dollars in out-of-pocket costs.[vii]

This study also projected the impact of legislation requiring robust coverage of biomarker testing, projecting an impact of $0.08-$0.51 per member per month. This does not account for any potential cost savings from avoiding ineffective treatments.[viii]

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Biomarker Testing: Beyond Oncology

Substantial progress has been made in the fight against cancer in recent decades, resulting in a 33% reduction in the cancer death rate since its peak in 1991.[i] As patients are living longer, and some cancers become more of a chronic condition, cancer patients and survivors are often living with one or more comorbidities (additional diseases or medical conditions) due to shared risk factors and side effects of cancer treatment.

- A recent study found that nearly 2 in 3 patients diagnosed with colorectal cancer, lung cancer, or Hodgkin's lymphoma had at least one comorbidity at the time of their diagnosis, and about half of patients had multiple comorbidities.[ii]
- According to the National Cancer Institute, the top four most commonly diagnosed cancers—lung, colorectal, breast, and prostate—have rates of comorbidity at 52.9%, 40.7%, 32.2%, and 30.5%, respectively for patients over age 66. [iii]
- **The most common comorbidities cancer patients and survivors face include diabetes, COPD, cardiovascular diseases (e.g., congestive heart failure, cerebrovascular disease, peripheral vascular disease), renal failure, and rheumatological conditions (e.g., osteoarthritis and rheumatoid arthritis).[iv]**
    - Anxiety is also more common in cancer patients, and patients with cancer are five times more likely to suffer from depression compared to the general population.[v]

While most current applications are in cancer, biomarker testing is becoming increasingly important to the treatment of other disease areas including rheumatoid arthritis, other autoimmune conditions, organ and tissue transplant, rare diseases, preeclampsia. Pharmacogenomic biomarker testing also guides treatment across a wide range of conditions. There is biomarker research happening in many other areas including Alzheimers, other neurological conditions, cardiology and more. Current non-oncology biomarker testing applications could be used to address common comorbidities in cancer patients and survivors and as personalized medicine continues to evolve, non-oncology biomarker testing applications will likely have an increasing role in guiding treatment for patients with and without a cancer diagnosis.

Biomarker Testing and Autoimmune and Autoinflammatory Arthritis Diseases

One in 10 people are living with autoimmune and autoinflammatory arthritis diseases.[vi] The average age of onset in adults is 20 – 40.[vii,viii,ix,x] Age of juvenile onset disease varies, but can happen in early childhood.[xi] While it is recommended to initiate treatment within six months of disease onset to increase the probability of remission[xii], it takes several years to get an accurate diagnosis for a majority of patients.[xiii] Due to several factors, including clinical trials that do not represent real world populations, comorbidities, and disease heterogeneity, only 40-60% respond well to existing treatments.[xiv,xv, xvi, xvii] It is estimated that as many as 70% of patients develop comorbidities (including dual diagnosis and conditions such as heart disease or Alzheimers).[xviii,xix] The standard arthritis treatment approach of trial-and-error further complicates therapy response. Biomarker testing can be an important tool to pinpoint diagnosis, understand prognosis, and develop treatment plans that improve quality of life and increase chances for remission.

Biomarkers are not new in the autoimmune and autoinflammatory arthritis disease space. For example, doctors often refer to elevated rheumatoid factor, anti-CCP, and antineutrophil cytoplasmic antibodies (ANCA) to assist in diagnosis and to predict worse outcomes in rheumatoid arthritis (RA).[xx] Some tests, like multi-biomarker disease activity (MBDA) blood tests, test for several biomarkers at one time to monitor disease activity and predict joint damage. While there are current applications, recent research continues to advance the use of biomarkers in rheumatology, which can aid in detection, diagnosis, and determining treatment response.

Current applications of biomarker testing for arthritis patients include:

Anti-CCP Antibody Testing for Rheumatoid Arthritis (RA)

Molecular signature response classifier (MSRC) tests monitor levels of specific antibodies and gene expressions which can help indicate a patient's likelihood to respond to tumor necrosis factor inhibitors (TNFi), a specific class of medications used to treat inflammatory conditions. A low score means the patient will be less likely to respond to these types of therapies. Ninety percent of RA patients are prescribed TNFi biologics as first line therapies, and better access to predictive biomarker testing could potentially improve health outcomes and lead to cost avoidance for millions of patients.[xxi]

Polyglutamate Testing

This testing measures the effectiveness of one of the most commonly prescribed drugs for RA. This test allows a provider to determine if the dose needs to be adjusted, or if the patient needs to be prescribed a different medication.

Biomarker Testing for Organ and Bone Marrow Transplants

Biomarker testing is used in bone marrow transplants to match patients and donors. A close match between a donor's and a patient's tissue markers is essential for a successful transplant outcome.[xxii] Biomarker testing is also critical in organ transplant to assess risks and monitor for rejection, with research happening on methods to utilize non-invasive biomarker testing to monitor for rejection and ultimately improve outcomes. While bone marrow transplants are best known for their use in the treatment of blood

cancers, biomarker testing is also essential for other disorders. For example, bone marrow transplants are used in the treatment of non-malignant chronic diseases such as Sickle Cell Disease.

Organ Rejection Status Testing

This type of testing analyzes donor derived cell-free DNA (dd-cfDNA) present in the bloodstream of a patient to determine if rejection of the transplanted organ is occurring. It is used to monitor a transplant patient for signs of rejection, allowing for modification of immunosuppressive therapy to maximize longevity. The cost for managing a failed transplant may be up to 500% more than a patient with a functioning transplant.[xxiii]

Sickle Cell Disease

Sickle cell disease is a chronic disorder which causes the body to make unhealthy red blood cells, causing organ damage, and need for a bone marrow transplant as a life-saving treatment. Beyond the implications of biomarker testing for bone marrow transplants to treat the disease, there is ongoing research in using biomarker testing to predict the risk of a patient with sickle cell disease experience vaso-occlusive crisis, which can result in severe pain and organ damage.[xxiv]

Biomarker Testing and Rare Diseases

A rare disease is defined in the United States as a disease or condition that impacts fewer than 200,000 people. There are more than 7,000 known rare diseases, affecting about 1 in 10 people in the United States.[xxv] Of the newly FDA approved personalized treatments in 2022, 35% were for the treatment of rare diseases[xxvi]. Personalized treatments often require biomarker testing prior to use to determine patient eligibility. Often, patients with rare diseases suffer while going undiagnosed or misdiagnosed for years. Biomarker testing often plays a critical role in rare diseases to establish or confirm a diagnosis and monitor disease progression and treatment effectiveness.

Biomarker Testing and Preeclampsia

The United States is the only developed country in the world where maternal morbidity and death rates are increasing.[xxvii] Hypertensive disorders of pregnancy, like preeclampsia, are a leading cause of these preventable deaths. Preeclampsia manifests with heightened maternal blood pressure and organ dysfunction, leading to severe complications like kidney and liver failure and cerebral edema. If left untreated (and in rare cases without preeclampsia symptoms), it can escalate to eclampsia, a condition categorized by seizures or a variant called HELLP Syndrome which can cause liver rupture, bleeding/clotting issues, and other morbidities.[xxviii] There is a disparate impact when it comes to maternal morbidity, with black women three times more likely to die from pregnancy-related complications compared to white women.[xxix]

Preeclampsia can vary in severity. Patients with a diagnosis should be monitored closely, but those at high risk of severe preeclampsia will likely remain in the hospital until delivery.

Prognostic sFlt1 and PlGF testing

This test measures two proteins in the blood to identify those at highest risk of developing severe preeclampsia.[xxx] The test helps providers to develop the appropriate treatment plan. Low-risk patients can

be monitored from home, alleviating financial and emotional burdens and reducing healthcare costs. Those at higher risk receive appropriately intensified care, increasing the likelihood of positive outcomes for both mother and baby.

Pharmacogenomic (PGx) Biomarker Testing

Pharmacogenomic (PGx) testing (also known as pharmacogenomic biomarker testing) is a component of precision medicine that involves examining a patient's inherited genes to detect variations that may impact the way a drug is broken down, absorbed and used within the body. Sometimes these variations can impact the safety and effectiveness of treatment. The same treatment given to patients with the same disease can produce different responses based on each person's inherited genes. There are a significant number of drug-gene pairs that can impact a patient's response to a medication, thus making PGx testing beneficial. These interactions are most common in oncology, neurology, cardiology, and infectious disease.

PGx Testing in Depression

Depression is the number one cause of disability in the United States for individuals ages 15-44.[xxxi] PGx biomarker testing can be used to inform the selection of prescription drugs to treat patients. This type of testing can help a provider to understand the way a patient's genomic make up may affect an individual's response to certain psychiatric drugs – including those used to treat depression. Selective serotonin reuptake inhibitors (SSRIs) are the most commonly used drugs to treat depression in adults.[xxxii] There are several genetic variants that may impact the effectiveness or safety of SSRIs.[xxxiii]

PGx biomarker testing made the difference for Julie, who was suffering from postpartum depression. After having an adverse reaction to the antidepressant that she was prescribed, an SSRI, she underwent PGx biomarker testing. The results showed that SSRIs may not be a good fit for her. Her doctor prescribed a different medication, and Julie credits that new medication with helping her feel like herself again:

> *"I felt defeated because these medications worked for others; why didn't they work for me? Now I know that's not how this works! Since being on a medication that is working for me, I am motivated, optimistic, and thriving – rather than trying to survive.*
>
> *-Julie L., Indiana*

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