May 3, 2023

The Honorable Senator Donna Bailey
The Honorable Representative Anne Perry
Committee on Health Coverage, Insurance and Financial Services

RE: Support for L.D.1577 An Act to Require Health Insurance Coverage for Biomarker Testing

Dear Chairs Bailey and Perry and Members of the Committee,

My name is Danielle Adams and I am the Managing Director of Advocacy for the ALS Association in New England. On behalf of the ALS Association and 66 patients we currently serve in Maine, I would like to express our support L.D.1577, An Act to Require Health Insurance Coverage for Biomarker Testing. This legislation would increase access to biomarker testing for more Mainers living with ALS and other diseases.

Biomarker testing is an essential step to accessing precision medicine that can lead to improved survivorship and better quality of life for patients. A biomarker is a molecular signature, like a protein or gene, that can provide insights into medical conditions for diseases like ALS, cancer, arthritis, and more. The results of a biomarker test give providers knowledge that can guide a patient's treatment plan, potentially providing access to targeted treatment that can improve disease outcomes, quality of life for patients, and reduce costs. In some cases, paying upfront for comprehensive testing can result in overall savings in treatment costs.

However, insurance coverage is failing to keep pace with innovations and advancements in treatment for serious diseases and conditions. 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. This bill would require state-regulated health insurance plans to cover comprehensive biomarker testing when supported by medical and scientific evidence.

While biomarkers are primarily used in oncology, more are being discovered every day and are in the research pipeline. Just two weeks ago, the FDA granted accelerated approval for Tofersen, a gene-based therapy for people with SOD1-ALS, a form of ALS found in about 20% of familial, or inherited cases. The accelerated approval pathway allows the FDA to approve drugs quickly based on a surrogate endpoint -- in this case, the biomarker neurofilament light, or NfL.

NfL levels in the blood and spinal fluid indicate damage that is happening to motor neurons. Tofersen was shown to reduce levels of NfL during the clinical trial. The advisory committee found that the NfL levels indicate a change in the course of disease for people receiving the treatment, which translates into benefits such as longer life, increased muscle function and reduced disease progression. This is important to note because we see that research is on its way to discovering biomarkers that can lead to quicker diagnosis and improved treatment pathways for patients living with ALS, a devastating and always-fatal disease.

Unfortunately, not all communities in the state are benefitting from the latest advancements in biomarker testing and precision medicine. Patients who are older, Black, uninsured or Medicaid-insured, live in rural communities, and those who get their care in a community setting versus academic medical centers, are less likely to be tested for certain guideline-indicated biomarkers. Without action, lack of access to biomarker testing could increase existing disparities in health outcomes by race, ethnicity, income, and geography.

Currently it takes 12-14 months for someone to be diagnosed with ALS, a disease with an average prognosis of 2-5 years, meaning they are further along in their journey before they begin receiving treatment. NfL can be a diagnostic biomarker, meaning it will help patients to be diagnosed quicker. It can also be a prognostic biomarker, meaning it will help determine if a patient will have a faster or slower disease progression, or if a particular drug is working. It is vital that biomarker testing is accessible to patients so they can receive a diagnosis earlier and get treated quicker.

When people living with ALS are already losing so much of their lives to this devastating disease, they should not have to worry about losing access to the extra time with their loved ones and the benefits that these tests can provide.

Thank you for your time and your consideration of this critical legislation. For all these reasons, I respectfully ask for your support on L.D.1577.

Sincerely,

Danielle Adams, MPH
Managing Director, Advocacy (New England)
ALS Association