Maine Chapter
INCORPORATED IN MAINE
American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

30 Association Drive, Box 190
Manchester, ME 04351
office: 207-480-4185

www.maineaap.org

Testimony in support of LD 1577, 'An Act to Require Health Insurance Coverage for Biomarker Testing'

Senator Bailey, Representative Perry and Distinguished Members of the Insurance and Financial Services Committee, my name is Dr. Alton Kremer. I am a resident of Falmouth Maine and a board member for the Maine Chapter of the American Academy of Pediatrics (Maine AAP).

I am a retired physician who spent most of his career developing new anti-cancer medications. In addition to the Maine AAP, I currently serve as a volunteer on the board of CancerCare, a charity supporting cancer patients and their families. I am testifying to support and urge passage of LD-1577, An Act to Require Health Insurance Coverage for Biomarker Testing. This bill is critically important because it addresses the very core of our ability to properly diagnose and treat patients. It is about access to needed health care.

Why is it so important?

It has become clear over the past decade or so that cancer is not one disease, even when we consider cancers by their tissue of origin, the way we have traditionally talked about cancer. Cancers are now defined by specific mutations, changes that occur in the genes of the cancer cell some of which drive them to become aggressive cancers. These mutations cause the production or over-production of specific proteins in these cells. These genes and/or the proteins they produce are the biomarkers. If we take the most common type of lung cancer (non-small cell lung cancer) as an example, in 2021 more than 70% of patients had a mutation driving the cancer.[1] This same subdivision of cancers by mutation occurs in breast cancer, melanoma, colorectal cancer and others.

Treating patients based on the precise mutation, the biomarker, in their cancers is what we call precision medicine or personalized medicine. This allows physicians to give patients the drug that they, individually, need to treat the disease that they have. We have made great strides in our ability to do this. As an example, in 2021, for seven lung cancers defined by specific mutations and biomarkers, over fifteen drugs had been approved by FDA[1] and more are coming.

Biomarker testing is necessary to use these new drugs. Over the past five years, 60% of the oncology drugs that have been launched need biomarker testing before they can be used[2]. Many of these drugs treat cancers with one specific mutation in the cancer, be it lung cancer, breast cancer, ovarian cancer or others. Other drugs, called tumor-agnostic, can treat cancers from multiple different tissues that have the same mutation or biomarker. The use of the immunotherapeutic drugs that have proven effective across a number of cancers in some settings also require biomarker testing. The approval of these drugs by the FDA is often in combination with a "companion diagnostic", a specific test that determines if the patient has the biomarker that the drug targets.[3] It is important to understand that if the safety and efficacy of a drug is shown only in people with a specific biomarker, then the FDA-approved label for the drug will restrict the indication to those people. This point derives from federal regulations and is clearly stated by FDA in their guidance[3]. Therefore, the use of these precision medicine cancer drugs in accordance with both labeling and clinical practice depends on the biomarker testing. Consequently, it is clear that biomarker testing is important to patients, to all of us.

Unfortunately, today not all patients who could benefit from these precision therapeutics actually receive them. One of the reasons for this is about the level of insurance coverage. Two-thirds of oncology health-care providers have reported insurance coverage as an issue in testing patients for biomarkers[4] and this then becomes a barricade against giving patients the treatments they need.

Precision medicine only works if we know the disease that the patient has. Biomarkers tell us the disease that the patient has and the drug the patient should receive. Biomarkers also tell us what drugs not to give. This is why it is so important to have insurance coverage for biomarker testing. Without biomarkers, we cannot deploy the weapons we have developed against cancer, and we cannot properly treat patients. Insurance coverage for biomarker testing, which this bill will provide, is essential in having the best treatment for cancer.

References:

1. Chevallier, M., et al, World J Clin Oncol, 2021, 12: 217-237
2. Global Oncology Trends, 2021, IQVIA Institute, June 2021
3. Food and Drug Administration Guidances: In Vitro Companion Diagnostic Devices, 2014, Principles for Codevelopment of an In Vitro Companion Diagnostic Device with a Therapeutic Product, 2016, and Developing and Labeling In vitro Companion Diagnostic Devices for a Specific Group of Oncology Therapeutic Products 2020
4. ACS CAN, Survey Findings Summary: Understanding Provider Utilization of Cancer Biomarker Testing Across Cancers, December 2021

Submitted by: Alton B. Kremer MD, Ph.D