June 28, 2021

Asm. Jim Wood, Chair
Assembly Health Committee
California State Legislature
Sacramento, CA 95814

Re: Senate Bill 535 (Limón) – Cancer Biomarker Testing

Assembly Member Jim Wood,

As organizations that represent hundreds of thousands of cancer patients and providers, we appreciate the opportunity to provide our support for California Senate Bill 535, introduced by Senator Limón, to eliminate prior authorization for cancer biomarker testing.

All cancers have genomic mutations, or biomarkers, that help to characterize the features of the cancer. Biomarker testing is thus a critical component of cancer care because it is essential for an accurate diagnosis and the identification of an optimal treatment plan. Many cancer mutations either already have FDA-approved treatments or have new treatments under clinical investigation. This creates an imperative for patients to be tested for the presence of biomarker(s) at diagnosis and at recurrence or progression of their disease, in accordance with clinical guidelines, so that they can be placed on the correct care plan and access the promise of precision medicine.

Delays in biomarker testing for cancer patients are not simply inconvenient; they can cause serious harm. Therefore, our organizations are supportive of Senate Bill 535, as it will remove barriers to biomarker testing.

Importance of biomarker-driven care in cancer treatment

Precision medicine is defined as biomarker-driven care, which includes both targeted therapies and immunotherapies as well as treatments in which a biomarker or lack of biomarker indicates another care path, such as chemotherapy**. Timely and affordable access to diagnostics that inform treatment decisions is critical for cancer patients**. In this era of unprecedented scientific advancements for the treatment of cancer, cancer patients diagnosed today have the advantage, opportunity, and right to learn about the unique biomarker profile of their cancer to direct them to the appropriate treatment option or clinical trial. **Utilization management strategies, such as prior authorization, cause unnecessary delays in patients' access to biomarker testing.**

Delays in biomarker testing may lead to delays in care as well as suboptimal care

Clinical guidelines, including those from the National Comprehensive Cancer Network, recommend advanced diagnostic testing as an important clinical tool to aid in identification of appropriate treatment options. **Anything that delays biomarker testing will delay when a patient can start his or her own individualized treatment plan. Prior authorization for biomarker testing has the potential to cause harmful delays for patients in addition to creating administrative burdens for healthcare professionals.** When health plans require prior authorization for biomarker testing for standard-of-care requests made in alignment with national guidelines, patients can experience an inexcusable delay, and sometimes a denial, of the lifesaving diagnostics that will direct them to timely access of critical therapies.

We have heard from numerous providers in California that some regional health plans routinely ask for prior authorization before approving standard-of-care biomarker testing, despite this testing being recommended for patients under NCCN guidelines. We also have learned that many prior authorization barriers are more commonly found for patients treated at community cancer centers, where most cancer patients are treated. Community cancer centers do not have the same level of staff personnel or resources that larger, academic cancer centers have to ensure coordination, contracting, and agreement with health plans that can help to streamline prior authorization processes. Our organizations are very concerned that prior authorization for biomarker testing:

- Obligates providers to seek time-consuming, insurer-imposed approvals that serve as a bottleneck to the provider's ability to follow NCCN guidelines and provide the best possible care for their patients.
- Causes providers to skip biomarker testing completely and start a patient on a therapy that may or may not work for that patient's unique cancer.

Delays in biomarker testing from prior authorization may not only impact the right treatment selection, but in fact may also lead to a patient getting matched to the **wrong** treatment. Prior authorization can be detrimental to patient outcomes if it serves as a deterrent to biomarker testing.

Our organizations support removing prior authorization for biomarker testing in accordance with NCCN guidelines

We are supportive of SB 535 for the potential it has to improve patient access to timely biomarker testing and, thus, access to the right drug at the right time. We are grateful for the opportunity to comment on SB 535, and are happy to discuss these comments should you have any questions.

Thank you for your attention to this very important matter.

Sincerely,

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