

Health Policy and Analytics Medicaid Waiver Renewal Team  
Attn: Michelle Hatfield  
500 Summer St. NE, E65  
Salem, OR 97301

**RE: Oregon's Draft Medicaid Demonstration 1115 Waiver Application**

Dear Ms. Hatfield,

The ALS Association of Oregon and Southwest Washington is concerned with the proposal by Oregon Health Authority to potentially restrict access for Medicaid patients to new ALS treatments. We request that you remove "Strategy 3" from the 1115 Medicaid Demonstration Waiver.

Our organization is the central source for services and education for people with Amyotrophic Lateral Sclerosis (ALS), their families, caregivers, and health care professionals in all of Oregon and the six counties of SW Washington. We provide a range of services: direct services to people with ALS including clinics, support groups, access to medical and speech equipment, funding cutting-edge research and generally connecting those whose lives have been impacted by ALS.

ALS is a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord. ALS robs people of their ability to walk, talk, eat and speak; it is always fatal disease with an average life expectancy for of 2-5 years from diagnosis. There is no current cure for ALS, and only a few drugs approved for treating various symptoms of ALS. The pipeline for ALS treatments depends on the FDA accelerated approval pathway, as ALS has a serious condition with unmet needs. Moreover, the short life expectancy of a person diagnosed with ALS makes every second count, whether in research, approval, access and treatment.

Stated plainly, there are very few reasons for people living with ALS and their families to be hopeful following diagnosis. The pipeline for new treatments is one thing they cling to, and the FDA accelerate approval process makes that hope real. Unfortunately, Oregon Health Authority's (OHA) draft 1115 Waiver application would create one more potential barrier for access if OHA determined that it would not cover a new, approved ALS drug. This would be crushing to a patient and family on Medicaid, already inundated with the challenges of coverage while facing a complex labyrinth of health care costs and administration in light of an impossible diagnosis.

While the ALS Association sympathizes with OHA's challenges in containing costs, focusing on the accelerate approval process as a mechanism for restricting access or reducing utilization is dangerously misplaced. The proposed language directly undermines the FDA's scientific approach for determining that a drug is safe and effective (and purports to replace it with a "rigorous state review process" which doesn't exist). Worse, the application specifically refers to accelerate approval drugs as drugs with "limited or inadequate evidence of clinical efficacy" which is plainly false and continues to undermine patients and the public's faith in scientific rigor. The purpose of the accelerated approval



**OUR VISION** Create a world without ALS.

**OUR MISSION** To discover treatments and a cure for ALS, and to serve, advocate for, and empower people affected by ALS to live their lives to the fullest.

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pathway is to benefit patients with conditions like ALS, where there are unmet medical needs and for those facing with rare diseases. It is NOT a shortcut for rigorous scientific review.

By law (21 U.S.C. § 356(e)(2)), FDA must find "substantial evidence of effectiveness" to approve any drug, including AA drugs. FDA and Congress have both made clear that neither FDASIA's accelerated approval provisions nor the 21<sup>st</sup> Century Cures Act diluted FDA's approval standards. There is no reason (nor evidence) that OHA current infrastructure, including Oregon's "Health Evidence Review Commission" or Pharmacy and Therapeutics Committee has the staff, expertise, resources to duplicate the FDA process. Any such review would be redundant, costing patients valuable time and options where treatments may be available.

Secondly, with rare disease, such as ALS, reducing access to drugs approved through the accelerated approval process won't provide meaningful savings for our state Medicaid program anyway (or at least OHA should demonstrate that it will). According to the American Journal of Managed Care, accelerated approval drugs have accounted for less than 1% of Medicaid spending consistently every year ([https://cdn.sanity.io/files/0vv8moc6/ajmc/29d6a18fc7af58d6df13f31652049db55f245756.pdf/AJMC\\_06\\_2021\\_Thorpe\\_final.pdf](https://cdn.sanity.io/files/0vv8moc6/ajmc/29d6a18fc7af58d6df13f31652049db55f245756.pdf/AJMC_06_2021_Thorpe_final.pdf)). Coupling the scientific rigor of the FDA process and the limited savings, there is no rational reason to seek authority to limit access to drugs for those with rare conditions or no other treatment options.

Further, the waiver application will create even more disparities in care and sends a message to Oregonians that those with high unmet need, rare conditions and needing access to new therapies are a lower priority for full Medicaid coverage. The disparity of care would only be magnified where people with ALS could access a new drug through a private insurance carrier, but low-income Oregonians seeking access through Medicaid may not (or worse, spend valuable time fighting a challenging prior authorization process while their condition continues to progress). While the value of accelerated approval drugs to our community is clear, has OHA provided evidence that excluding these drugs would result in savings to the state system? If not, this is a significant risk to patient access and their hopes and realization of better quality of life with no clearly established benefits flowing to the state.

On a broader scale, these types of proposals only further discourage innovation for diseases like ALS where the only viable pathway to bring a treatment to market is the accelerated approval pathway. With so many conditions where investment and research can provide a quicker (and already more certain) return on investment, OHA's application would only increase our community's challenges in finding researchers and companies who will focus on treatments for ALS.

On a final note, we are also concerned with the request for the state to create a closed formulary. Again, this change is counter to Oregon's purported goal of the 1115 waiver: "to eliminate inequitable access with strategies to extend and stabilize coverage to every eligible child and adult in Oregon." In addition to the few ALS treatment currently available, ALS patients rely on an array of drugs to deal with the myriad symptoms of a degenerative neurological condition. Medicaid patients should have access to the drugs their providers prescribe without OHA preliminarily determining which have more value.

OHA's Section 1115 demonstration amendment request to exclude new drugs approved under the FDA's accelerated approval pathway is misplaced and potentially significantly damaging for patients

with rare conditions and unmet needs. It could very likely lead to perverse disparities in care and limit options for ALS patients on state Medicaid.

We urge you to remove Strategy 3 from the waiver application.

Thank you,

A handwritten signature in dark ink, reading "Lance Christian". The signature is written in a cursive, flowing style. The first name "Lance" is written in a larger, more prominent script, and the last name "Christian" follows in a similar but slightly smaller script. The ink appears to be a dark grey or black.

Lance Christian  
Executive Director