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Interim Deputy Medicaid Director Dana Hittle
500 Summer St. NE, E65
Salem, OR 97301

Submitted via email to: 1115Waiver.Renewal@dhsosha.state.or.us

Dear Interim Deputy Director Hittle:

The TSC Alliance appreciates the opportunity to comment on the Oregon 1115 Demonstration Waiver for the Oregon Health Program (OHP). This waiver contains multiple proposals that would be catastrophic to the rare epilepsy community, who rely on complex care management with as few unnecessary hurdles as possible. As there are many individuals within the rare epilepsy community with refractory epilepsy it is imperative that therapy options remain accessible to meet these serious unmet medical needs.

The TSC Alliance is a 501(c)(3) non-profit organization dedicated to finding a cure for tuberous sclerosis complex (TSC), while improving the lives of those affected. We drive research, increase care quality and access, inspire hope and advocate with and for all affected by the disease. TSC is a rare genetic disorder that can cause tumor growth in all the body's vital organs. Symptoms can include seizures, kidney failure, brain and lung tumors, autism spectrum disorder and severe learning disabilities. TSC is also the leading genetic cause of both epilepsy and autism.

As with many rare disease organizations, our constituents are left with minimal treatment options, if any. We are very concerned with the new proposed closed formulary for adults, as well as Oregon's proposals to continue the waiver of retroactive eligibility, and continue to waive the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit for children over the age of one and continued use of a Prioritized List of services that relies, in part, on a quality-adjusted life year. Approval of these proposals eliminate options that give our loved ones hope and valuable time that many individuals desperately need to avoid irreversible damage, complications, and death.

Hope no matter how complex



Oregon's proposal would allow the state to exclude FDA-approved drugs entirely. Failure to allow already FDA-approved drugs for our community is ethically unacceptable and detrimental to those individuals living with epilepsy. By suggesting the state could offer just one drug per therapeutic class for our population will not only increase overall healthcare burden that many of these individuals face, these individuals and families will also experience higher hospitalizations, increased missed work for adults with epilepsy and caregivers, and decreased overall quality of life. Restricting appropriate medications and irresponsibly determining prescription practices outside of the physician – patient collaboration is harmful and can be avoided.

Additionally, Oregon proposes to continue to eliminate retroactive coverage for nearly all beneficiaries excluding those eligible through a disability pathway. Retroactive eligibility for our community is essential to expediting critical discovery and evaluations that if left untreated can lead to life altering and even fatal consequences. Furthermore, without this eligibility our community faces another burden of financial costs and delays that continue to widen the gap of healthcare disparities and access to care for our rare disease community. We are also concerned with the existence of the Prioritized List at all, and further concerned about the use of QALYs to determine who gets care. QALYs discriminate against people with disabilities by devaluing lives lived with disability.

Equally, we are opposed to the restricted coverage for treatment under Early and Periodic Screening, Diagnostic and Treatment. We strongly support the removal of the restrictions to the EPSDT benefit to allow children full and equitable access to healthcare, in keeping with the purpose of the EPSDT benefit for Screening, Diagnosis and Treatment (EPSDT). As you are aware, management for most conditions do not solely focus on medications, especially those within our community where care is complex and multifaceted. In addition to seizures, subependymal giant cell astrocytoma (SEGA) is a slow growing tumor that can cause life-threatening complications by blocking the flow of fluid in the brain and remains a major clinical feature associated with TSC.^{1,2} Given the complexity of tumor burden and location not all individuals are surgical candidates leaving these individuals with fatal complications. Devices such as Vagus Nerve Stimulation (VNS) and other medically appropriate devices that improve epilepsy are helpful to our population. 80% of those with TSC are affected by epilepsy and two-thirds are medically refractory. Early intervention is key to quality cognitive outcomes for those living with TSC. Limitations to services that are paramount in providing optimal evidence-based care for this population will further add to sub-optimal care for these families, especially those who are low-income.

The TSC Alliance appreciates the opportunity to comment on this proposal. We strongly hope that you consider our concerns so that those within the epilepsy and rare disease community can continue to obtain access to medications and services they need. If you have any questions or need further information, please do not hesitate to contact Chief Executive Officer, Kari Rosbeck, at krosbeck@tsalliance.org or Director of Medical Affairs, Ashley Pounders MSN, FNP-C, at apounders@tsalliance.org.

Sincerely,



Kari Luther Rosbeck
President and CEO



Ashley Pounders, MSN, FNP-C
Director of Medical Affairs

References

1. Arroyo MS, Krueger DA, Broomall E, Stevenson CB, Franz DN. Acute Management of Symptomatic Subependymal Giant Cell Astrocytoma With Everolimus. *Pediatr Neurol*. 2017;72:81-85. doi:10.1016/j.pediatrneurol.2017.04.008
2. Northrup H, Krueger DA, Roberds S, et al. Tuberous sclerosis complex diagnostic criteria update: Recommendations of the 2012 international tuberous sclerosis complex consensus conference. *Pediatr Neurol*. 2013;49(4):243-254. doi:10.1016/j.pediatrneurol.2013.08.001