April 13, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Re: Oregon Health Plan 1115 Demonstration

Dear Secretary Becerra:

The American Kidney Fund appreciates the opportunity to provide comments on the Oregon Health Plan 1115(a) Demonstration.

The American Kidney Fund (AKF) fights kidney disease on all fronts as the nation’s leading kidney nonprofit. AKF works on behalf of the 37 million Americans living with kidney disease, and the millions more at risk, with an unmatched scope of programs that support people wherever they are in their fight against kidney disease—from prevention through transplant. Through programs of prevention, early detection, financial support, disease management, clinical research, innovation and advocacy, no kidney organization impacts more lives than AKF. AKF is one of the nation’s top-rated nonprofits, investing 97 cents of every donated dollar in programs, and holds the highest 4-Star rating from Charity Navigator and the Platinum Seal of Transparency from GuideStar.

AKF appreciates certain proposals in Oregon’s demonstration waiver that aim to eliminate gaps in coverage and advance health equity. However, we focus our comments on Oregon’s proposal to limit coverage of drugs approved through the Food and Drug Administration’s (FDA) accelerated approval pathway (AAP). We oppose this proposal as it will create a barrier for patients to access new and life-saving treatments.

While diabetes and high blood pressure are the most common causes of kidney disease, rare diseases can also lead to chronic kidney disease and kidney failure. Although classified as rare among the general population, at least ten percent of adults and almost all children who receive renal replacement...
therapy have an inherited rare kidney disease. Rare kidney diseases also disproportionately affect communities of color, particularly Black Americans. More resources are needed to improve early diagnosis, better understand ways to slow the progression of rare kidney disease and improve treatments for rare kidney disease. One of the essential tools to improve access to treatments is the AAP, and limiting access to existing or future medications for rare kidney diseases that are approved through the AAP would mean Medicaid patients in Oregon could be denied access to potentially life-saving treatments. While we applaud Oregon’s focus on advancing health equity in its Medicaid program, this proposal would do the opposite, as it would exacerbate health disparities by denying access to treatments for low-income Medicaid patients while patients with private health coverage would be able to access drugs approved through the AAP.

Oregon’s proposal would also fail to uphold the core statutory objective of the Medicaid program, which is “to furnish medical assistance [to individuals] whose income and resources are insufficient to meet the cost of necessary medical services.” In its waiver application, the state says that “[t]hrough this process, the state could incentivize drug sponsors to complete their regulatory obligations to demonstrate clinical benefit as laid out by the FDA upon approval.” However, the state does not describe how this would meet the objective of the Medicaid program. Rather, the proposal would deny access to a potentially life-saving, FDA-approved medication that is available to patients with private coverage. Also, it is not the responsibility of the state, through a demonstration waiver, to ensure manufacturers are meeting FDA requirements in the drug approval process.

For years, the Medicaid program has had an open formulary to ensure vulnerable populations, including low-income children, adults, seniors and people with disabilities can access the medications that they need. Oregon’s proposal would significantly undermine this critical patient protection and put the care of these populations at risk. We therefore urge HHS to reject the state’s proposal to limit or exclude treatments approved though the FDA’s accelerated approval pathway.

Thank you for the opportunity to provide comments on Oregon’s Medicaid waiver application.

Sincerely,

Holly Bode
Vice President of Government Affairs

   https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4135047/