



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 Waiver

Dear Secretary Becerra:

Thank you for the opportunity to comment on Oregon's Section 1115 Demonstration Waiver. On behalf of people with cystic fibrosis (CF) living in Oregon, we commend the state for not renewing its waiver of the Early and Periodic Screening, Diagnosis and Treatment (EPSDT) benefits, eliminating its waiver for retroactive coverage, and including multi-year continuous eligibility in this application. However, we are concerned that the state's request to exclude coverage for medications based on their Food and Drug Administration (FDA) approval pathway will endanger patient access to care and therefore urge the Centers for Medicare and Medicaid Services (CMS) to reject the state's request to implement this policy.

Cystic fibrosis is a life-threatening genetic disease that affects more than 30,000 children and adults in the United States, including nearly 500 in Oregon. Roughly a third of adults and children living with CF in the state rely on Oregon Health Plan (OHP) for some or all of their health care coverage. CF causes the body to produce thick, sticky mucus that clogs the lungs and digestive system, which can lead to life-threatening infections. As a complex, multi-system condition, CF requires targeted, specialized treatment and medications. If left untreated, infections and exacerbations caused by CF can result in irreversible lung damage and premature death, usually by respiratory failure. While advances in CF care are helping people live longer, healthier lives, we also know that cost is a barrier to care for many people with the disease and comprehensive coverage is vital to ensuring that people with CF can access the care and treatments they need.

Given the vital role Medicaid plays in helping this patient population access essential specialized care, we urge CMS to consider the needs of people living with CF as the state seeks changes to OHP. The Cystic Fibrosis Foundation offers the following comments on Oregon's 1115 waiver:

Exclude drugs with limited or inadequate evidence of clinical efficacy from the formulary

While we appreciate that the state has removed the proposed closed formulary in response to feedback at the state level, we remain concerned that the revised proposal could still create significant barriers to coverage. Oregon requests the authority to use its own review process to determine whether drugs approved under the FDA accelerated approval process are covered by OHP. The state maintains that many drugs coming to market through FDA's accelerated approval pathways have not yet demonstrated clinical benefit.

We strongly oppose Oregon's proposal to create its own review process and waive its obligation to cover all FDA-approved drugs beyond certain excepted classes. While we understand the state's goal of incentivizing sponsors to complete confirmatory trials, the FDA remains the authority to enforce post-market requirements and determine whether drugs are safe and effective. Permitting states to set up parallel review processes could lead to the creation of duplicative and potentially less rigorous and less transparent processes. States should not have the authority to categorically exclude drugs based on the approval pathway; all FDA approvals are full approvals and should be covered as such. Oregon's proposal to categorically exclude therapies based on approval pathway will undermine the FDA's authority as the arbiter of safety and efficacy and set a precedent that could create barriers to needed medications for patients.

In addition to our overall opposition to this proposal, we note that the state's proposal does not include an appeals process for patients to access drugs that the state chooses to exclude or what criteria would be used to evaluate such appeals. Similarly, the state does not define the process for determining "limited or inadequate evidence of clinical efficacy" for the medications that Oregon may review. These lacking details are further cause for concern as we seek to understand the implications for patients with cystic fibrosis.

EPSDT Benefit

We applaud Oregon for not renewing its waiver of EPSDT benefits in this application. However, we remain concerned that there will still be unnecessary barriers to accessing EPSDT benefits for children. Oregon has proposed reviewing and revising the list of medically necessary services that will be covered for children but has not provided sufficient detail about how medical necessity will be determined when updating the list. For those services not included on the list of prioritized services, OHP would require further individual review. Patients who need such services will likely face an administrative burden in trying to access their care, potentially delaying the start or continuation of vital treatments. There are also no details on the appeals or exceptions process and how patients can access services not included on the list. We recommend that Oregon removes the list of prioritized services for both adults and children to meaningfully improve access to care for OHP members. Should the state receive approval to continue requiring additional "medical necessity" reviews for deprioritized services, we would request that Oregon provide transparency around this process and additional opportunities for stakeholders to comment as the prioritized list of health services is revised to account for EPSDT.

Continuous Eligibility

The Foundation supports the state's request for continuous enrollment for children under six and two-year continuous eligibility for beneficiaries over the age of six. Continuous eligibility protects Medicaid enrollees, including those with CF and other complex medical needs, from gaps in coverage that can lead to patients skipping care or facing high out-of-pocket costs. Specifically, research has shown that individuals with disruptions in coverage during a year are more likely to delay care, receive less preventive care, refill prescriptions less often, and have more emergency department visits.¹ We thank the state for prioritizing continuity of care.

Retroactive Eligibility

We also commend the state for removing its proposal to eliminate retroactive coverage for OHP members. Retroactive eligibility helps adults living with CF in Oregon who rely on Medicaid avoid gaps in

¹ <https://aspe.hhs.gov/sites/default/files/private/pdf/265366/medicaid-churning-ib.pdf>

coverage and costly medical bills. Cystic fibrosis care and treatments are costly, even with coverage, and retroactive eligibility helps protect against additional out-of-pocket costs.

According to a survey conducted by George Washington University of 1,800 people living with CF and their families, over 70 percent indicated that paying for health care has caused financial problems such as being contacted by a collection agency, having to file for bankruptcy, experiencing difficulty paying for basics like rent and utilities, or having to take a second job to make ends meet. And while nearly 75 percent received some form of financial assistance in 2019 to pay for their care, almost half reported still having problems paying for at least one medication or service in that same year.² Retroactive eligibility allows patients who have been diagnosed with a serious illness, such as cystic fibrosis, to begin treatment without being burdened by medical debt prior to their official eligibility determination.

The Cystic Fibrosis Foundation appreciates the opportunity to provide input on these important policy changes. We look forward to working with the state of Oregon to ensure access to high-quality, specialized CF care and improve the lives of all with cystic fibrosis. Please contact Sage Rosenthal, State Policy Specialist, at srosenthal@cff.org or (301) 841-2631 with any questions or comments.

Sincerely,

Mary B. Dwight
Chief Policy & Advocacy Officer
Senior Vice President, Policy & Advocacy
Cystic Fibrosis Foundation

Aaron Trimble, MD
Assistant Professor of Medicine
Adult Cystic Fibrosis Program Director
Division of Pulmonary, Allergy, and Critical Care
Oregon Health & Science University

Mike Powers, MD
Pediatric Cystic Fibrosis Program Director
Oregon Health & Science University

² Seyoum, Semret; Regenstein, Marsha; and Nolan, Lea, "Cost, coverage, and the underuse of medications among people with CF" (2020). Health Policy and Management Issue Briefs. Paper 57.
https://hsrc.himmelfarb.gwu.edu/sphhs_policy_briefs/57