CYSTIC FIBROSIS FOUNDATION®

January 7, 2022

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

Re: Oregon Health Plan 1115 Demonstration Waiver

Dear Deputy Director Hittle,

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 write to express our serious concerns with this waiver application. While we commend the state for its focus on health equity and inclusion of multi-year continuous eligibility in this application, we have serious concerns that several other proposals could create barriers to access care for people with cystic fibrosis (CF). Specifically, our comments below focus on the requests to adopt a commercial-style closed drug formulary, implement an internal review process to evaluate new drugs for clinical effectiveness, and eliminate retroactive coverage for nearly all beneficiaries.

Cystic fibrosis is a life-threatening genetic disease that affects more than 35,000 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. Through careful, aggressive, and continuously improving disease management, the average life expectancy for people with cystic fibrosis has risen steadily over the last few decades. In addition to advances in care, recently approved genetically-targeted drugs that address the underlying cause of CF are available for patients with specific genetic profiles and have contributed to the increases in life expectancy. This milestone reflects over 50 years of hard work to improve CF treatments, develop evidence-based standards of care, and encourage adherence to a lifetime of chronic care. However, despite immense progress in recent decades, there is still critical work to be done to ensure that all those living with the disease have access to effective therapies and, ultimately, a cure.

Given the vital role Medicaid plays in helping this patient population access essential specialized care, we urge Oregon to consider the needs of people living with CF as the state seeks changes to OHP. Within Oregon's' 1115 demonstration request, we are particularly concerned with the following provisions:

Adopt a commercial-style "closed formulary"
Oregon seeks to waive the requirement that Medicaid provide at least some coverage for all FDA-approved drugs and instead implement a commercial-style closed formulary to include at least one drug available per therapeutic class. The CF Foundation recognizes the reality that growth in drug costs contributes to the increasing strain on state budgets. However, we are concerned that the adoption of a closed formulary could create barriers to accessing necessary, life-saving treatments.

Treatments for CF are finite and not interchangeable; more than one drug per class is necessary in some therapeutic areas such as CFTR modulators, inhaled antibiotics, and pancreatic enzymes. For example, inhaled antibiotics are an important part of the CF care regimen. Because the type of antibiotic, the dosage, and the length of time to take the drug all vary from person to person—and the fact that some people become resistant to antibiotics over time—it is critical that people with CF have access to all available inhaled antibiotics designed specifically for CF.

Similarly, access to all CFTR modulators, the only class of CF therapies to address the underlying cause of the disease, is necessary due to the highly individualized nature of cystic fibrosis. Ivacaftor (Kalydeco®), lumacaftor/ivacaftor (Orkambi®), tezacaftor/ivacaftor (Symdeko®), and elexacaftor/ivacaftor/tezacaftor (Trikafta®) are FDA-approved therapies that improve the function of CFTR protein for individuals with specific mutations in the CFTR gene. Different CFTR mutations cause different defects in the protein; therefore, genetically targeted modulators are effective only in people with specific mutations, and multiple therapies are needed within the same class to ensure everyone has access. Individual treatment regimens for CF are best determined between a patient and their CF care team.

This application also states that there will be pharmacy protections so that the adoption of a commercial-style formulary does not negatively impact members' access to safe, effective drugs. However, we are alarmed that the waiver does not outline what these pharmacy protections will be, nor does it include an exception process or any other mechanism for patients to access medically necessary drugs that are not on the formulary. This proposal lacks clear detail and fails to specify exactly how this process will work or how the state would ensure patient access. Oregon should articulate a clearly defined exceptions process, including a timeline for decisions that protects patients from delays. The state should also ensure that this exceptions process does not create an undue burden for providers.

Exclude drugs with limited or inadequate evidence of clinical efficacy from the formulary
Oregon requests the authority to use its own review process, in partnership with the Coordinated Care Organizations (CCOs), to determine whether drugs 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. However, this waiver could apply more broadly to any drug, with the state noting that it will prioritize any new drugs (not just accelerated approval drugs) as well as re-formulations of existing drugs.

Furthermore, the state's plan to adopt a closed formulary must include more specificity and transparency. This waiver application states that Oregon would use its "own rigorous review process" to develop the OHP formulary but does not provide any information about how coverage decisions would be made, how the state would ensure transparency around this process, or how it would result in timely access to therapies for members. Should the state receive approval for its commercial-style formulary, it must provide a clearly defined and transparent review process, with opportunities for public review and comment, including significant input from experts, such as CF clinicians.

Remove retroactive eligibility
We are also concerned with this waiver's request to extend the elimination of retroactive coverage for almost all beneficiaries. Retroactive eligibility helps adults living with CF in Oregon who rely on Medicaid avoid gaps in 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.[1] 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.

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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 Sr. Coordinator, at srosenthal@cff.org or (301) 841-2631 with any questions or comments.

Sincerely,

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[1] 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