CYSTIC FIBROSIS FOUNDATION®

Heather O'Toole, M.D., M.S., M.P.H.
Vice President
Chief Medical Officer
SelectHealth
5381 S Green Street
Murray, UT 84123

CC:
Jonathan T. Pike, Insurance Commissioner, Utah Insurance Department
Dean Cameron, Director, Idaho Department of Insurance
Scott Kipper, Insurance Commissioner, Nevada Division of Insurance
Michael Conway, Insurance Commissioner, Colorado Division of Insurance

Dear Dr. O'Toole:

On behalf of the nearly 40,000 children and adults living with cystic fibrosis (CF) – including over 1,500 in Utah, Idaho, Nevada, and Colorado – we write in response to SelectHealth's removal of CFTR modulators (ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor) from marketplace and small employer plan formularies. **We insist SelectHealth immediately update their formularies to cover these essential treatments in compliance with the patient protections as required under the Affordable Care Act (ACA).** We are alarmed to see this restrictive coverage in place, especially after your refusal to discuss CFTR modulators in June and your lack of response to our July 31st, 2023 letter about clinically inappropriate coverage criteria for elexacaftor/tezacaftor/ivacaftor. We request you and your team schedule time to meet with us to discuss this issue further.

About cystic fibrosis
Cystic fibrosis is a life-shortening genetic disease resulting from mutations in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene that causes the body to produce thick, sticky mucus that clogs the lungs and digestive system. There is no cure for CF today. As a complex, multi-system condition, CF requires targeted, specialized treatment and medications. As the world's leader in the search for a cure for CF and an organization dedicated to ensuring access to high quality, specialized CF care, the Cystic Fibrosis Foundation supports the development of CF clinical practice guidelines and accredits more than 130 care centers and 35 affiliate programs nationally. Given the progressive nature of cystic fibrosis, it is imperative that people with CF have timely access to health care to minimize disease progression and prevent any health declines.

About CFTR modulators
As shared in our previous letter sent on July 31st, 2023, CFTR modulators are the most significant therapeutic advancement in CF to date. These oral therapies are the only medications available that address the underlying cause of cystic fibrosis – CFTR protein defects – in individuals with specific mutations in the *CFTR* gene. CFTR modulators are associated with improvements in lung function and body mass index and decreased exacerbations which in turn leads to stability in lung function.[1] Longer-term data supports that these

[1] Cystic Fibrosis Foundation Patient Registry 2021 Annual Data Report Bethesda, Maryland ©2022 Cystic Fibrosis Foundation

improvements are sustained over time.[2] Restoring CFTR function preserves health and lung function, reduces costly hospitalizations, improves quality of life, delays the need for lung transplantation, and improves survival. To further highlight the efficacy and clinical benefits of these treatments, we have attached to this letter a summary of key research on just one of the modulators: elexacaftor/tezacaftor/ivacaftor.

Cystic fibrosis experts agree that CFTR modulators are the clinically appropriate first line therapy for people with cystic fibrosis – with the specific modulator treatment taken depending on the person's age and genetic profile. It is imperative that people with CF initiate modulator therapy as soon as patients and their physicians determine it is medically appropriate, as it may prevent or slow future CF complications.

Discriminatory practice of removing CFTR modulators

The ACA contains provisions barring discriminatory plan benefit design, establishing that a Qualified Health Plan (QHP) may "not employ marketing practices or benefit designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs."[3] Removing critical therapies like CFTR modulators from plan formularies will directly discourage people with CF from enrolling in these plans and therefore should be considered discriminatory benefit design under federal regulation. Furthermore, as updated in the 2023 Notice of Benefit and Payment Parameters, a benefit design that limits coverage must be clinically-based to be considered nondiscriminatory. As identified above (and attached), there is significant data to demonstrate the clinical benefits of CFTR modulators as a class of drugs, and therefore removing these therapies would be in violation of the EHB protections.

People with cystic fibrosis require timely, uninterrupted access to specialized care and treatments to manage the disease. **We demand SelectHealth cover CFTR modulators on their marketplace and small employer plan formularies as indicated by the FDA label**.

We request that we schedule a time to meet to further discuss this issue. Please contact Olivia Dieni, Manager, Healthcare Access at odieni@cff.org or 240-200-3715.

Thank you for your prompt attention to this matter.

Sincerely,

Bruce C. Marshall, MD
Executive Vice President
Chief Medical Officer

Mary B. Dwight
Senior Vice President
Chief Policy and Advocacy Officer

[2] Lee T, Sawicki GS, Altenburg J, Millar SJ, Geiger JM, Jennings MT, Lou Y, McGarry LJ, Van Brunt K, Linnemann RW. Effect of elexacaftor/tezacaftor/ivacaftor on annual rate of lung function decline in people with cystic fibrosis. J Cyst Fibros. 2022 Dec 27:S1569-1993(22)01429-1. doi: 10.1016/j.jcf.2022.12.009. Epub ahead of print. PMID: 36581485.

[3] 45 C.F.R. § 156.200(e)