



February 1, 2021

Dr. Lee A. Norman
Secretary, Kansas Department of Health and Environment

Dear Secretary Norman:

On behalf of the approximately 380 people living with cystic fibrosis in Kansas, we write today to urge the state to ensure people with high-risk conditions – including cystic fibrosis – are prioritized for early access to COVID-19 vaccines. We recognize the monumentally difficult task public health officials face when creating allocation plans that are both equitable and actionable during this crisis, and we appreciate the immense effort state public health departments have put into creating plans to allocate limited supplies of COVID-19 vaccines. However, we are deeply concerned that the state’s vaccine plans would deny people with CF the ability to access COVID-19 vaccines alongside others with high-risk conditions, despite guidance from the CDC.¹

Our comments below urge the state to immediately revise its vaccine prioritization plan to ensure those with CF are prioritized for access to COVID-19 vaccines with others with high-risk conditions in phase 3 of the state’s vaccine prioritization plan.

Background on Cystic Fibrosis and COVID-19

The Cystic Fibrosis Foundation is a national organization actively engaged in the research and development of new therapies for cystic fibrosis – a rare, life-threatening genetic disease that affects more than 30,000 people in the United States. The buildup of thick, sticky mucus in the lungs characteristic of the disease makes people with CF particularly prone to chronic respiratory infections. These chronic infections are punctuated by pulmonary exacerbations, events that are a risk factor for an irreversible decline of lung function and associated with morbidity and mortality. A significant proportion of pulmonary exacerbations are triggered by respiratory viral infections. With continued progress of the disease, some individuals with CF and advanced lung disease pursue lung transplantation.

The absent or malfunctioning protein that causes CF is also associated with a wide range of disease manifestations beyond the lungs, including pancreatic insufficiency that can lead to malnutrition, gastrointestinal issues, biliary cirrhosis, and diabetes mellitus.

While we have seen incredible progress in recent decades for those living with cystic fibrosis, COVID-19 represents a serious threat for this population. The strongest evidence to date on the threat COVID-19 poses to those with CF comes from a global analysis of 181 COVID-19 cases among people with CF.²

¹ <https://www.kansasvaccine.gov/DocumentCenter/View/121/Vaccine-Prioritization-Slides-PDF>

² Cosgriff, Rebecca et al. “The global impact of SARS-CoV-2 in 181 people with cystic fibrosis.” *Journal of Cystic Fibrosis* (2020), in press

From that analysis, it appears CF patients with advanced lung disease, those that are post-lung transplantation, and those with diabetes mellitus may be at risk of severe outcomes including death.

Due to the known risks posed by viral infections and multi-system manifestations of the disease described above, people with CF should be considered at increased risk of poor outcomes from COVID-19 infection and the Centers for Disease Control and Prevention (CDC) has listed CF as a condition that may put individuals at increased risk for worse outcomes.³

Individuals with Cystic Fibrosis Must Be Prioritized for Access to COVID-19 Vaccines

We are concerned that Kansas has deprioritized people with CF for COVID-19 vaccines compared to other conditions that are known to increase the risk of severe illness from COVID-19 infection. We urge Kansas not to override the allocation recommendations put forth by the CDC’s Advisory Committee on Immunization Practices (ACIP) and to heed further CDC guidance on the limitations of evidence for rare disease patients and the need for physician discretion in identifying individuals for early vaccine access.

The CDC’s designation of CF as a condition that *may* increase the risk of severe disease from COVID-19 is due, in part, to a lack of evidence—which is unavoidable for a rare disease. As a small patient population, it has been challenging to gain a clear picture about how COVID-19 affects people with CF. However, we believe the CDC’s designation may mischaracterize the true risk for some people living with the disease, especially those with advanced lung disease and those who are post-transplant.

In fact, the CDC acknowledges the limitations of available evidence on COVID-19’s impact for many disease groups, including rare diseases like CF.⁴ The ACIP vaccine allocation recommendations, which include persons aged 16 to 64 years with high-risk medical conditions in phase 1c, are also accompanied by important CDC guidance on the limitations of available evidence and a recommendation to use clinical judgement in identifying patients whose individual risks factors warrant priority vaccine access.⁵ States should incorporate the additional CDC guidance into their allocation plans by including language about using clinical discretion to identify high-risk individuals and including rare diseases, like CF, on lists of high-risk conditions.

We urge Kansas to revise the state’s COVID-19 vaccine prioritization plan so that people with CF and other rare diseases that may increase the risk of worse outcomes from COVID-19 infection can get vaccines alongside other patients with high-risk conditions. We further ask Kansas to ensure clinician discretion may be used in identifying additional individuals at high-risk for prioritization purposes.

Once again, we thank you for your attention and consideration of people with CF as you tackle these difficult issues. It is critical that all state COVID-19 vaccination plans ensure early vaccine access for both diseases with large populations capable of generating clear evidence on the risks of COVID-19 and other

³ <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>

⁴ <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>

⁵ <https://www.cdc.gov/vaccines/covid-19/phased-implementation.html>

rare disease populations too small to generate similar evidence. We look forward to working with you as the state continues to revise and develop further allocation recommendations for COVID-19 vaccines.

Sincerely,

A handwritten signature in black ink, appearing to read "Mary B. Dwight", written in a cursive style.

Mary B. Dwight

Chief Policy and Advocacy Officer
Senior Vice President of Policy and Advocacy
Cystic Fibrosis Foundation