



February 8, 2021

Marylou Sudders
Secretary
Executive Office of Health and Human Services
Commonwealth of Massachusetts

Dear Secretary Sudders:

On behalf of the approximately 810 people living with cystic fibrosis in Massachusetts, we write today to urge the state to ensure people with high-risk medical 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 plan would deny people with CF the ability to access COVID-19 vaccines alongside others with high-risk conditions, despite guidance from the CDC about prioritizing rare disease populations.¹

Our comments below urge Massachusetts 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 the state's vaccine prioritization plan. We also call on the state to provide equal access to individuals with one high-risk condition as those with multiple comorbidities included in phase 2, group 2 of the state's vaccine 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.

¹ <https://www.mass.gov/info-details/massachusetts-covid-19-vaccination-phases#phase-2->

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 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 Massachusetts' plan excludes people with CF from priority COVID-19 vaccine access by limiting prioritized populations to those with conditions known to increase the risk of severe illness from COVID-19 infection. We urge the state to follow 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 CDC Advisory Committee on Immunization Practices vaccine allocation recommendations, which include persons aged 16 to 64 years with high-risk medical conditions in phase 1c, are accompanied by important CDC guidance on the limitations of available evidence and a recommendation to use clinical judgement in identifying patients whose individual risks 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 Massachusetts 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 the state to ensure clinician discretion may be used in identifying additional individuals at high-risk for prioritization purposes.

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

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>

Individuals with One High-Risk Condition Should be Prioritized for Access to COVID-19 Vaccines

We also urge Massachusetts to give equal priority to anyone with a condition that puts them at high-risk for severe disease from COVID-19 instead of prioritizing those with two or more comorbid conditions. We recognize the need for sub-group prioritization due to limited vaccine supplies. However, a focus on multiple conditions neglects other indications of disease severity or vulnerability. For instance, someone with cystic fibrosis who received a double lung transplant is especially vulnerable to complications from COVID-19, as they are taking medication to suppress their immune system. Those with advanced disease may also be particularly vulnerable. However, under an allocation scheme prioritizing those with two or more high-risk comorbid conditions according to the CDC, individuals with advanced disease would receive a vaccine after someone with a body mass index above 30 and COPD. We believe that this scenario inappropriately disadvantages someone who should be prioritized for early access to a vaccine, and we recommend removing the criteria related to multiple conditions.

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 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,



Mary B. Dwight

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

CC: The Honorable Charlie Baker, Governor of Massachusetts