



September 23, 2021

Grace M. Lee, MD, MPH  
Chair, Advisory Committee on Immunization Practices (ACIP)  
1600 Clifton Road, NE  
Mailstop A27  
Atlanta, GA 30329

Re: CDC-2021-0104, ACIP Meeting, September 22 – 23, 2021

Dear Dr. Lee:

On behalf of the Cystic Fibrosis Foundation, we ask ACIP to provide clarity on COMIRNATY booster dose eligibility and ensure people with CF are included in the definition of “high-risk.” As we explain below, those with CF are at increased risk of severe COVID-19 disease and should be eligible for a booster dose. However, because people with CF have not always been included in the definition of high-risk individuals (particularly at the state level), we recommend clarity on this point.

#### **Background on cystic fibrosis**

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 intractable bacterial infections. These chronic airway 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 as well. Viral infections may be particularly acute in people with CF due to a diminished innate antiviral response in CF cells, which show weaker induction of interferon and expression of some interferon-stimulated genes, as compared to non-CF controls. Continued progression of the disease can result in advanced lung disease so severe that lung transplantation may be the only life extending option.

#### **Cystic fibrosis and COVID-19**

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 comes from a published global analysis of 181 COVID-19 cases among people with CF made possible through an international collaboration of 19 countries including the US.<sup>1</sup> 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 increased risk of severe outcomes including death.

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<sup>1</sup> E. McClenaghan, R. Cosgriff, K. Brownlee et al., “The global impact of SARS-CoV-2 in 181 people with cystic fibrosis,” *Journal of Cystic Fibrosis*, <https://doi.org/10.1016/j.jcf.2020.10.003>

As a result of this data analysis and the risks posed by viral infections described above, the CDC includes cystic fibrosis as a condition that may increase the risk of poor outcomes from COVID-19 infection.<sup>2</sup>

**Eligibility for booster doses**

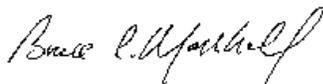
As the ACIP considers usage recommendations for COMIRNATY booster doses, it is imperative to include people with CF in the definition of those at high-risk for severe disease. Despite data demonstrating the increased risk of poor outcomes for some people with CF, cystic fibrosis was not listed as a high-risk condition for early vaccine eligibility in some states. As a small population with less published data on the impact of COVID-19 compared to other diseases, cystic fibrosis was overlooked or deprioritized relative to larger disease populations that can more clearly articulate the effect of COVID-19 infection. As we look toward additional vaccine doses for certain populations, it is critical that the ACIP include people with cystic fibrosis along with other high-risk conditions.

Additionally, patients struggled to navigate unclear, confusing guidelines about vaccine eligibility in the early days of COVID-19 vaccine administration, exacerbating the ongoing anxiety experienced by many living with serious, chronic conditions during this pandemic. As the ACIP considers a usage recommendation, we urge clarity and specificity to minimize potential confusion and assure patients about their eligibility to receive a booster dose when appropriate.

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We thank you for your attention and consideration of people with cystic fibrosis as you tackle these difficult issues.

Sincerely,



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



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

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<sup>2</sup> <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html#copd>