



September 21, 2021

Peter Marks, MD, PhD
Director, Center for Biologics Evaluation and Research
Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Booster Dose for COMIRNATY for Populations at High-Risk for Severe COVID-19

Dear Dr. Marks:

On behalf of the Cystic Fibrosis Foundation, we write to urge that the COMIRNATY emergency use authorization (EUA) under consideration by the Food and Drug Administration (FDA) include people with cystic fibrosis among those eligible for boosters. As we explain below, those with CF are at high-risk of severe COVID and should be included in an EUA that follows the advice of the Vaccines and Related Biological Products Advisory Committee (VRBPAC). However, because people with CF have not always been included (particularly at the state level) in the definition of high-risk individuals, we recommend clarity on this point.

We understand that the VRBPAC unanimously supported boosters for people 65 years of age and older and those at high-risk of severe disease. The advisors also offered advice about health care workers and others whose work may put them at high risk of contracting COVID-19. We are pleased by the committee action and ask that FDA ensure the recommendation and advice of the advisory panel are clearly reflected in the EUA.

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.¹ 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.

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.²

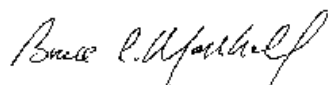
Eligibility for booster doses

As the FDA considers the language of the EUA and the high-risk populations who would benefit from additional doses of COMIRNATY and other COVID-19 vaccines, 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 FDA grant an EUA that is clear regarding its application to people with cystic fibrosis and 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 agency moves forward on the EUA application and then the Advisory Committee on Immunization Practices and Centers for Disease Control and Prevention consider a usage recommendation, we urge the agencies to provide clear guidance about the EUA and usage recommendation. Clarity in the language of the EUA, the usage recommendation, and the supporting educational materials will minimize potential confusion and assure patients about their eligibility to receive a booster dose when appropriate.

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

¹ 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>

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