



March 30, 2022

FDA Authorizes Second Booster Dose of Two COVID-19 Vaccines for Older and Immunocompromised Individuals

On March 29, 2022, the U.S. Food and Drug Administration (FDA) authorized a second booster dose of either the [Pfizer-BioNTech](#) or [Moderna](#) COVID-19 vaccines for older people and certain immunocompromised individuals. The FDA previously authorized a single booster dose for certain immunocompromised individuals following completion of a three-dose primary vaccination series. This action will now make a second booster dose of these vaccines available to other populations at higher risk for severe disease, hospitalization and death. Emerging evidence suggests that a second booster dose of an mRNA COVID-19 vaccine improves protection against severe COVID-19 and is not associated with new safety concerns.¹

The FDA amended the emergency use authorizations as follows¹:

- A second booster dose of the **Pfizer-BioNTech COVID-19 Vaccine or Moderna COVID-19 Vaccine** may be administered to individuals 50 years of age and older at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine.
- A second booster dose of the **Pfizer-BioNTech COVID-19 Vaccine** may be administered to individuals 12 years of age and older with certain kinds of immunocompromise at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine. These are people who have undergone solid organ transplantation, or who are living with conditions that are considered to have an equivalent level of immunocompromise.
- A second booster dose of the **Moderna COVID-19 Vaccine** may be administered at least 4 months after the first booster dose of any authorized or approved COVID-19 vaccine to individuals 18 years of age and older with the same certain kinds of immunocompromise.

This action applies only to the Pfizer-BioNTech and Moderna COVID-19 vaccines and the authorization of a single booster dose for other age groups with these vaccines remains unchanged. The agency will continue to evaluate data and information as it becomes available when considering the potential use of a second booster dose in other age groups.¹

The FDA-authorized Pfizer-BioNTech COVID-19 Vaccine and the FDA-approved Comirnaty[®] can be used to provide the authorized booster dose(s). Similarly, the FDA-authorized Moderna COVID-19 Vaccine and the FDA-approved SpikeVax[®] are authorized to provide the authorized booster dose(s).

Information to Support Authorization of a Second COVID-19 Booster Dose¹:

A summary of safety surveillance data provided to the FDA by the Ministry of Health of Israel on the administration of approximately 700,000 fourth (second booster) doses of the Pfizer-BioNTech COVID-19 Vaccine given at least 4 months after the third dose in adults 18 years of age and older (approximately 600,000 of whom were 60 years of age and older) revealed no new safety concerns.² The safety of Moderna COVID-19 Vaccine, when administered as a second booster dose, is informed by experience with the Pfizer-BioNTech COVID-19 Vaccine and safety information reported from an

independently conducted study in which the Moderna COVID-19 Vaccine was administered as a second booster dose to 120 participants 18 years of age and older who had received a two-dose primary series and a first booster dose of Pfizer-BioNTech COVID-19 Vaccine at least 4 months prior. No new safety concerns were reported during up to three weeks of follow up after the second booster dose.

Immunogenicity data from an ongoing, open-label, non-randomized clinical study in healthcare workers at a single center in Israel were reported in a publication provided to the FDA. In this study, individuals 18 years of age and older who had received primary vaccination and a first booster dose with Pfizer-BioNTech COVID-19 Vaccine were administered a second booster dose of Pfizer-BioNTech COVID-19 Vaccine (154 individuals) or Moderna COVID-19 Vaccine (120 individuals) at least four months after the first booster dose. Among these individuals, increases in neutralizing antibody levels against SARS-CoV-2 virus, including delta and omicron variants were reported two weeks after the second booster as compared to 5 months after the first booster dose.¹

CDC Action(s): CDC Recommends Additional Boosters for Certain individuals³

Following the FDA's regulatory action, the CDC updated its recommendations to allow certain immunocompromised individuals and people over the age of 50 who received an initial booster dose at least 4 months ago to be eligible for another mRNA booster to increase their protection against severe disease from COVID-19.

Separately and in addition, based on [newly published data](#), adults who received a primary vaccine and booster dose of Johnson & Johnson's Janssen COVID-19 vaccine at least 4 months ago may now receive a second booster dose using an mRNA COVID-19 vaccine.

These updated recommendations acknowledge the increased risk of severe disease in certain populations including those who are elderly or over the age of 50 with multiple underlying conditions, along with the currently available data on vaccine and booster effectiveness.

Current EUA Fact Sheets⁴

As a convenience, Fact Sheets for Pfizer-BioNTech and Moderna COVID-19 vaccines are accessible below:

- Healthcare Providers (Pfizer-BioNTech)
 - ❖ [For 12 years of age and older – DILUTE BEFORE USE](#) (Pfizer-BioNTech)
 - ❖ [For 12 years of age and older – DO NOT DILUTE](#) (Pfizer-BioNTech)
 - ❖ [For 5 to 11 years of age](#) (Pfizer-BioNTech)
- Patients, Parents and Caregivers (Pfizer-BioNTech)
 - ❖ [For 12 years of age and older](#) (Pfizer-BioNTech)
 - ❖ [For 5 to 11 years of age](#) (Pfizer-BioNTech)
- [Healthcare Providers](#) (Moderna)
 - ❖ [Primary Series and Booster Dose Presentation](#) (Moderna)
 - ❖ [Booster Dose Only Presentation](#) (Moderna)
- [Patients, Parents and Caregivers](#) (Moderna)

References:

1. U.S. Food and Drug Administration. FDA NEWS RELEASE. [Coronavirus \(COVID-19\) Update: FDA Authorizes Second Booster Dose of Two COVID-19 Vaccines for Older and Immunocompromised Individuals](#). Published March 29, 2022.
2. Arbel R, Sergienko R, Friger M, et al. [Second Booster Vaccine and COVID-19 Mortality in Adults 60-100 years old](#). *Research Square* (pre-print). Posted Date: March 24th, 2022.
3. U.S. Centers for Disease Control and Prevention. [CDC recommends Additional Boosters for Certain Individuals](#). Published March 29, 2022.
4. U.S. Food and Drug Administration. [Coronavirus Disease 2019 \(COVID-19\) EUA information: VACCINES](#). Accessed March 30, 2022.