



August 16, 2021

FDA Authorizes Additional Vaccine Dose for Certain Immunocompromised Individuals (UPDATES to the Emergency Use Authorizations) Pfizer-BioNTech (BNT162b2) & Moderna (mRNA-1273) COVID-19 Vaccines

On December 11, 2020, the U.S Food and Drug Administration (FDA) issued an Emergency Use Authorization for the Pfizer-BioNTech COVID-19 Vaccine for prevention for COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older. May 10, 2021, the FDA reissued and expanded the Pfizer-BioNTech COVID-19 Vaccine EUA to include individuals aged 12 to 15 years. It is not currently FDA-approved for any indication.

On December 18, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for mRNA-1273 (the Moderna COVID-19 Vaccine) for prevention of COVID-19 in individuals 18 years of age and older. It is not currently FDA-approved for any indication.

On August 12, 2021, the FDA amended¹ the Emergency Use Authorizations (EUAs) for both the Pfizer BioNTech COVID-19 Vaccine² and the Moderna COVID-19 Vaccine,³ noting the following;

- **Authorization of the use of an additional dose in certain immunocompromised individuals, specifically, solid organ transplant recipients or those who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.**

According to the Centers for Disease Control and Prevention, approximately 2.7% of U.S. adults are immune compromised.⁴ In its [news release](#),¹ the FDA noted that immunocompromised people are especially at risk for severe disease. After a thorough review of the available data, the FDA determined that this small vulnerable group may benefit from a third dose of the Pfizer-BioNTech or Moderna Vaccines. It is important to note that;

- **Currently, there is insufficient evidence to support additional doses of the Johnson and Johnson/Janssen COVID-19 Vaccine (or additional mRNA vaccination for Janssen Vaccine recipients) for immunocompromised people.**
- **Other individuals who are fully vaccinated are adequately protected and do not need an additional dose of COVID-19 vaccine at this time.**

The basis for the FDA's action to amend the Emergency Use Authorizations for the mRNA COVID -19 vaccines includes two studies published in the *New England Journal of Medicine*, which demonstrated improved immunogenicity of the vaccines among persons with solid organ transplants.^{5,6,7}

CDC Advisory Committee on Immunization Practices (ACIP)⁸:

On August 13, 2021, the ACIP met to review information related to the FDA's amended EUA. The ACIP noted that immunocompromised people are more likely to have breakthrough infection, more likely to get severely ill from COVID-19, have lower antibody/neutralization titers to SARS-CoV-2 variants, more likely to transmit SARS-CoV-2 to household contacts, and higher risk for prolonged SARS-CoV-2 infection and shedding.

The population of moderately and severely immunocompromised people under consideration included;

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge, Wiskott-Aldrich syndromes)
- Advanced or untreated HIV infection

- Active treatment with high-dose corticosteroids (i.e., ≥ 20 mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, TNF blockers, and other biologic agents that are immunosuppressive or immunomodulatory

The ACIP voted to recommend an additional dose of Pfizer-BioNTech COVID-19 vaccine (≥ 12 years) or Moderna COVID-19 vaccine (≥ 18 years) following a primary series in immune-compromised people.

Implementation Guidance:

- The additional dose should be the same mRNA vaccine as the primary series.
- Alternate mRNA product can be used if primary series product not available.
- Until more data are available, the additional dose should be administered at least 28 days after completion of the initial primary series.

According to the CDC’s Interim Clinical Considerations for Use of COVID-19 Vaccines, the clinical benefit of an additional mRNA vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series for immunocompromised people is not precisely known. However, for people with moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments, the potential to increase immune response coupled with an acceptable safety profile, support the recommendation for an additional mRNA vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series.

As a convenience, the accompanying **EUA Fact Sheets** are accessible immediately below.

1. Fact Sheet, Pfizer-BioNTech COVID-19 Vaccine – [For Healthcare Providers](#) (HCP)
2. Fact Sheet, Pfizer-BioNTech COVID-19 Vaccine – [Patients, Parents, and Caregivers](#)
3. Fact Sheet, Moderna COVID-19 Vaccine – [For Healthcare Providers](#)
4. Fact Sheet, Moderna COVID-19 Vaccine – [Patients, Parents, and Caregivers](#)

Mandatory Requirements under the EUAs:^{9,10}

- Use Pfizer-BioNTech and Moderna COVID Vaccine only in authorized patient populations described in respective Fact Sheets (HCP).
- Communicate to patients or parents/caregivers, as age appropriate, information consistent with the “Fact Sheet for Patients, Parents and Caregivers” prior to patient receiving Pfizer-BioNTech and Moderna COVID-19 Vaccine.
- Include vaccination information in the state/local jurisdiction’s Immunization Information System (IIS) or other designated system.
- Respond to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer BioNTech or Moderna COVID-19 Vaccine to recipients.
- Mandatory reporting of the following to the [Vaccine Adverse Event Reporting System \(VAERS\)](#):
 - *Vaccine administration errors whether or not associated with an adverse event,*
 - *Serious adverse events (irrespective of attribution to vaccination),*
 - *Cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and*
 - *Cases of COVID-19 that result in hospitalization or death.*
- **Should include the words “Indian Health Service” or “IHS” on the form in item #26.**

References:

1. [News Release](#): FDA Authorizes Additional Vaccine Dose for Certain Immunocompromised Individuals, August 12, 2021.
2. U.S. Food and Drug Administration. [Letter of Authorization](#) (EUA) Reissued: Pfizer-BioNTech COVID-19 Vaccine, August 12, 2021.
3. U.S. Food and Drug Administration. [Letter of Authorization](#) (EUA) Reissued: Moderna COVID-19 Vaccine, August 12, 2021.
4. Harpaz et al. *Prevalence of Immunosuppression Among US Adults*, 2013. JAMA 2016.
5. Kamar, N, Abravenel, F et al. Three doses of an mRNA COVID-19 Vaccine in Solid-Organ Transplant Recipients, *N Engl J Med* 385:661-662, Aug 12, 2021. <https://www.nejm.org/doi/full/10.1056/NEJMc2108861>.
6. Hall VG, Ferreira VH, Ku T, et al. Randomized trial of a third dose of mRNA-1273 vaccine in transplant recipients. *N Engl J Med*, Aug 12, 2021. <https://www.nejm.org/doi/full/10.1056/NEJMc2111462>.
7. Williams Winifred W., Ingelfinger Julie R., (2021) Third Time’s a Charm- COVID-19 Vaccine Hope for Solid-Organ Transplant Recipients. *N Engl J Med*, Aug 12, 2021. <https://www.nejm.org/doi/full/10.1056/NEJMe2112866>.
8. Advisory Committee on Immunization Practices (ACIP) Presentation Slides: [August 13, 2021 Meeting](#).
9. U.S. Food and Drug Administration. [Fact Sheet for Healthcare Providers](#). Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine. August 12, 2021.
10. U.S. Food and Drug Administration. [Fact Sheet for Healthcare Providers](#). Emergency Use Authorization (EUA) of Moderna COVID-19 Vaccine. August 12, 2021.