COVID-19 Additional Doses FAQs
(8-16-2021)

Definitions:

1. **Additional dose**: A dose of a vaccine that is given to people who did not experience a sufficient immune response to their primary vaccine series. The extra dose is intended to produce a sufficient immune response.
2. **Booster dose**: A dose of a vaccine that is given if someone has experienced a sufficient immune response from a primary vaccine series, but the immune response begins to wane over time.

**Q**: Do we need boosters given the contagiousness of the Delta variant?

**A**: The vaccines continue to be highly effective at protecting against serious illness and the Delta variant for people ages 12 and up. At this time, the CDC and Advisory Committee on Immunization Practices (ACIP) do not recommend booster doses for the general public.

**Q**: What if I’m immunocompromised? Should I ask for an additional dose of a COVID-19 vaccine?

**A**: On Aug. 12, the U.S. Food and Drug Administration (FDA) adjusted the existing Emergency Use Authorizations (EUA) for the Pfizer and Moderna COVID-19 vaccines to allow immunocompromised people to receive a third dose of either vaccine.

A third dose of the Pfizer vaccine may be administered at least 28 days following the second dose of a two-dose regimen to immunocompromised people ages 12 and older.

A third dose of the Moderna vaccine may be administered at least 28 days following the second dose of a two-dose regimen to immunocompromised people ages 18 and older.

Whenever possible, it is recommended to get the same brand of vaccine as you received for your original series. If that vaccine type is not available, then it is ok to obtain the other mRNA vaccine. The CDC advises fully vaccinated people with compromised immune systems to continue wearing a mask when in public, avoiding crowds and poorly ventilated indoor spaces, and staying six feet apart from others they don’t live with.
Q: Who is considered immunocompromised under the updated EUA?
A: According to the FDA statement, “immunocompromised individuals” are defined as solid organ transplant recipients or others who have similar reductions in their immune response.

The ACIP also expanded the FDA’s definition of “immunocompromised individuals” to include people who:

- Are undergoing active treatment for solid tumor and hematologic malignancies
- Have received solid-organ transplant and are taking immunosuppressive therapy
- Have received CAR (chimeric antigen receptor)-T-cell or hematopoietic stem cell transplant (within two years of transplantation or are taking immunosuppression therapy)
- Have moderate or severe primary immunodeficiency (e.g., DiGeorge, Wiskott-Aldrich syndromes)
- Have advanced or untreated HIV infection
- Are undergoing active treatment with high-dose corticosteroids (i.e., ≥20mg 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

Q: If I’m immunocompromised, can I call a vaccine provider to schedule an additional dose?
A: If you meet one or more of the conditions used to describe an “immunocompromised individual” under the guidelines of this EUA, you should talk with your health care provider to determine if you are eligible for an additional dose of an mRNA vaccine.

If you are, you will be required to self-attest to your immunocompromised condition before receiving an additional dose of your vaccine.

Q: Will the additional dose be the same amount as previous doses?
A: Yes, any immunocompromised people who elect to receive an additional dose of one of the mRNA vaccines will receive the same amount of vaccine as had previously been administered.

Q: Can the additional dose be different from the primary mRNA vaccine series?
A: In the instance that the primary mRNA vaccine that a person received is not available and they meet the age criteria for the alternate mRNA vaccine, they may receive a dose of an mRNA vaccine different from their primary mRNA vaccine.
Q: What do providers need to know about safety and reporting after administering a third dose?

A: Providers should be monitoring for safety events, including local and systemic reactions. Providers are encouraged to report any adverse reactions to the Vaccine Adverse Events Reporting Database (VAERS). https://vaers.hhs.gov

Q: What if an immunocompromised person received a Johnson & Johnson vaccine?

A: At this time, the CDC does not have enough data to suggest that an additional dose of the Johnson & Johnson vaccine would produce an enhanced immune response in an immunocompromised person and it is not recommended to receive an additional dose of Johnson & Johnson or an mRNA vaccine. These recommendations will be reviewed as this data becomes available.

Q: How many people will be affected by the updated EUA and will there be enough vaccines available to meet this potential demand?

A: The CDC estimates that approximately 3% of the U.S. population is considered immunocompromised based on the criteria provided. This approximation, however, is just an estimate.

Q: Did the emergence of the Delta variant compel the FDA and CDC to change the EUA for Pfizer and Moderna?

A: While the conversations about additional doses were had before the Delta variant began spreading, the Delta variant is influencing all conversations that are being had currently around COVID-19 protocols and prevention.

Q: Why weren’t certain conditions that would typically be considered immunocompromising included in the EUA adjustment?

A: “Immunocompromised individuals” encompasses a broad range of people. However, the CDC wanted to make sure that the recommendation for an additional dose only applied to those people who did not experience a sufficient immune response from a primary vaccine series. People who are at higher risk for COVID-19, but who have been shown to experience a sufficient immune response from a COVID-19 vaccine series, were not included in the adjusted EUA. The graph below displays some of the CDC’s findings.
These documents provide more information on vaccine recommendations in immunocompromised people:

- **ACIP Altered Immunocompetence Guidelines for Immunization**
- **2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host**
- **CDC Yellow Book 2020**

**Q: What about the use of monoclonal antibodies as a preventive measure?**

**A:** The FDA has authorized **monoclonal antibody treatments** for emergency use in individuals who are 12 years of age and older, weigh at least 88 pounds and are at high risk for severe COVID-19 or hospitalization.

For providers with concerns about fully vaccinated people who may be immunocompromised, monoclonal antibody therapy has now been expanded to include post-exposure prophylaxis for people who are fully vaccinated but immunocompromised. Monoclonal antibody therapy is now available in subcutaneous and intravenous form.

Monoclonal antibody treatments are not a substitute for vaccination.

**Q:** What if my doctor prescribed an additional mRNA dose to me and I am not immunocompromised?

**A:** Boosters are not authorized under the FDA emergency use authorization (EUA) for people who are not immunocompromised. The COVID-19 vaccine provider agreement does not allow for off-label use of the vaccine, including additional doses such as a
second dose after a Johnson & Johnson or a third dose after a Pfizer or Moderna series. Additional doses recommended by a doctor beyond the EUA scope should be discussed directly with the manufacturer and FDA.

Under the provider agreements in the CDC COVID-19 Vaccination Program, providers are required to administer COVID-19 vaccines in conformance with CDC/ACIP guidance.

**Q:** Is an immunocompromised patient who has only received two doses of an mRNA vaccine now only considered partially vaccinated?

**A:** No. According to CDC officials, the definition of a fully vaccinated individual will not change based on this new decision. People who have received either one dose of a Johnson & Johnson vaccine or two doses of an mRNA vaccine are considered fully vaccinated. Moderately to severely immunocompromised individuals, however, should understand their increased risk for COVID-19 infection and consider a third dose of an mRNA vaccine if they fit the criteria laid out in the updated EUA.

**Q:** Will Oregon be implementing the ACIP recommendation for additional doses?

**A:** The Western States Safety and Scientific Advisory committee discussed the ACIP recommendation and endorsed the use of additional doses of mRNA vaccines in eligible immunocompromised individuals. Patients and providers are encouraged to discuss the benefits and risks of additional doses to determine individual decisions for additional doses. Additional information can be found on the CDC clinical considerations page: [https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html)

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