



October 25, 2021

****Emergency Use Authorization** (UPDATED)**

**Booster doses authorized for Moderna & Janssen COVID-19 vaccines;
Heterologous “mix and match” booster administration also authorized**

Background¹:

On October 20th, 2021 the U.S. Food and Drug Administration took action to expand the use of a booster dose for COVID-19 vaccines in eligible populations. The agency is amending the emergency use authorizations (EUA) for COVID-19 vaccines to allow for the use of a single booster dose as follows:

- The use of a single booster dose of the Moderna COVID-19 Vaccine that may be administered at least 6 months after completion of the primary series to individuals:
 - 65 years of age and older
 - 18 through 64 years of age at high risk of severe COVID-19
 - 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2
- The use of a single booster dose of the Janssen (Johnson and Johnson) COVID-19 Vaccine may be administered at least 2 months after completion of the single-dose primary regimen to individuals 18 years of age and older.
- The use of each of the available COVID-19 vaccines as a heterologous (or “mix and match”) booster dose in eligible individuals following completion of primary vaccination with a different available COVID-19 vaccine.
- To clarify that a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine may be administered at least 6 months after completion of the primary series to individuals 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2.

Authorization of Moderna COVID-19 Vaccine Booster Dose¹:

To support the EUA of a single booster dose of Moderna COVID-19 Vaccine, the FDA analyzed data from 149 participants ≥ 18 years of age from the original clinical studies who received a booster dose at least 6 months after their second dose and compared it to the immune responses of 1,055 study participants after completing their two-dose series. The antibody response of the 149 participants against SARS-CoV-2 virus 29 days after a booster dose of the vaccine demonstrated a booster response.

Safety was evaluated in 171 participants ≥ 18 years of age who were followed for an average of six months. The most commonly reported side effects by the clinical trial participants who received the booster dose of the vaccine were pain at the injection site, tiredness, headache, muscle and/or joint pain, chills, swollen lymph nodes in same arm as the injection, nausea and vomiting, and fever. Of note, swollen lymph nodes in the underarm were observed more frequently following the booster dose than after the primary two-dose series.

The Moderna COVID-19 single **booster** dose is **half of the dose** that is administered for a primary series dose and is administered at least six months after completion of a primary series of the vaccine.

Authorization of Janssen COVID-19 Vaccine Booster Dose¹:

The authorization for emergency use of a single booster dose of the Janssen COVID-19 Vaccine is based on the FDA's evaluation of immune response data in 39 participants from a clinical trial including 24 participants who were 18 through 55 years of age and 15 participants who were 65 years of age and older. The study participants received a booster dose approximately 2 months after their first dose, and the results demonstrated a booster response.

Overall, approximately 9,000 clinical trial participants have received two doses of Janssen COVID-19 Vaccine administered at least two months apart and of these, approximately 2,700 have had at least two months of safety follow-up after the booster dose. Janssen's safety analyses from these studies have not identified new safety concerns.

Earlier analyses from the FDA and CDC safety surveillance systems suggest an increased risk of a serious and rare type of blood clot in combination with low blood platelets following administration of the Janssen COVID-19 vaccine. This serious condition is called thrombocytopenia syndrome (TTS). People who developed TTS after receiving the vaccine had symptoms that began about one to two weeks after vaccination. Reporting of TTS has been highest in females ages 18 through 49 years. In addition, safety surveillance suggests an increased risk of a specific serious neurological disorder called Guillain Barré syndrome, within 42 days following receipt of the Janssen COVID-19 Vaccine.

Authorization of the Heterologous “Mix and Match” Booster Dose¹:

The FDA also authorized the use of heterologous (or “mix and match”) booster dose for currently available (i.e., FDA-authorized or approved) COVID-19 vaccines. Following a presentation of clinical trial data, the VRBPA Committee’s discussion of information submitted for consideration, along with the agency’s evaluation of the available data, the FDA has determined that the known and potential benefits of the use of a single heterologous booster dose outweigh the known and potential risks of their use in eligible populations.

A single booster dose of any of the available COVID-19 vaccines may be administered as a heterologous booster dose following completion of primary vaccination with a different available COVID-19 vaccine. The eligible population(s) and dosing interval for a heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination.

For example, Janssen COVID-19 Vaccine recipients 18 years of age and older may receive a single booster dose of Janssen COVID-19 Vaccine, Moderna COVID-19 Vaccine (half dose) or Pfizer-BioNTech COVID-19 Vaccine at least two months after receiving their Janssen COVID-19 Vaccine primary vaccination. In another example, Moderna COVID-19 Vaccine and Pfizer-BioNTech COVID-19 vaccine recipients falling into one of the authorized categories for boosters (65 years of age and older, 18 through 64 years of age at high-risk of severe COVID-19, and 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2) may receive a booster dose of Moderna COVID-19 Vaccine (half dose), Pfizer-BioNTech COVID-19 Vaccine or Janssen COVID-19 Vaccine at least six months after completing their primary vaccination.

CDC Advisory Committee on Immunization Practices (ACIP) Interim Clinical Considerations²:

Summary of recent changes (last updated October 25, 2021):

- Updated guidance in section on [Considerations for use of a COVID-19 booster dose](#)
- New section added on [Overview of COVID-19 vaccines recommendations](#)
- Updated guidance in section on [COVID-19 vaccine dosage and schedule](#)
- Updated guidance in section on [People vaccinated for prevention of COVID-19 outside the United States](#)
- Updated guidance in section on [COVID-19 vaccination and SARS-CoV-2 infection](#) for People with prior or current SARS-CoV-2 infection; People with a history of multisystem inflammatory syndrome in children (MIS-C) or adults; People who received passive antibody products; and Vaccinated people who subsequently develop COVID-19
- New guidance on Considerations for COVID-19 revaccination in the section on [Considerations for COVID-19 vaccination in moderately and severely immunocompromised people](#)
- Updated Table in [Appendix A: Vaccine administration errors and deviations](#)

Current EUA Fact Sheets³⁻⁵:

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

1. Pfizer-BioNTech COVID-19 Vaccine: (1) [Healthcare Providers](#) -or- (2) [Recipients and Caregivers](#)
2. Moderna COVID-19 Vaccine: (1) [Healthcare Providers](#) -or- (2) [Recipients and Caregivers](#)
3. Janssen COVID-19 Vaccine: (1) [Healthcare Providers](#) -or- (2) [Recipients and Caregivers](#)

Mandatory Requirements under the EUAs:

- Use Pfizer-BioNTech, Moderna and Janssen COVID Vaccines only in authorized patient populations described in the respective Fact Sheets.
- Communicate to recipients or caregivers, as age appropriate, information consistent with the “Fact Sheet for Recipients and Caregivers” prior to receiving Pfizer-BioNTech, Moderna or Janssen COVID-19 Vaccines.
- Include vaccination information in the local jurisdiction’s Immunization Information System or other system.
- 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.
- 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, Moderna or Janssen COVID-19 Vaccines to recipients.
- Federal, Tribal, and Urban programs are all encouraged to **put “IHS” into field #26 of the form.**

References:

1. U.S. Food and Drug Administration (FDA). FDA News Release. [Coronavirus \(COVID-19\) Update: FDA Takes Additional Actions on the Use of a Booster Dose for COVID-19 Vaccines](#). October 20, 2021.
2. CDC Advisory Committee on Immunization Practices (ACIP). [Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the US](#). October 25, 2021.
3. FDA Fact Sheet for Healthcare Providers; Recipients and Caregivers. Pfizer-BioNTech COVID-19 vaccine. Assessed Oct 22, 2021. Available [here](#).
4. FDA Fact Sheet for Healthcare Providers; Recipients and Caregivers. Moderna COVID-19 vaccine. Assessed October 22, 2021. Available [here](#).
5. FDA Fact Sheet for Healthcare Providers; Recipients and Caregivers. Janssen COVID-19 vaccine. Assessed October 22, 2021. Available [here](#).