



IMMUNIZING PHARMACIST NEWS



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December 1, 2021

Important Updated Guidance from CDC

Update 1: CDC Updates COVID-19 Booster dose Recommendation

All persons aged 18 years and older **should receive** a booster dose of COVID-19 vaccine (Table 2). Pregnant people can receive any of the FDA-approved or FDA-authorized COVID-19 vaccines as a booster dose. Currently, CDC does not recommend a booster dose in children aged 5–17 years. As more data become available, this recommendation may be updated.

CDC has also updated information regarding [people who received COVID-19 vaccine outside the United States](#) and [people who received COVID-19 vaccine as part of a clinical trial](#). These should be consulted for booster dose recommendations in these groups.

Interval between primary series and booster doses

Any of the FDA-authorized or FDA-approved COVID-19 vaccines can be used for booster vaccination, regardless of the vaccine product used for primary vaccination. If a heterologous vaccine product is used for the booster dose, the interval should follow the interval recommended by the primary series; e.g., people who received a single dose Janssen primary series can receive an mRNA COVID-19 vaccine booster dose at least 2 months (8 weeks) after completing their Janssen primary series. If the booster dose is given earlier than the 4-day grace period³ (i.e., administered more than 4 days before 6 months after a second mRNA primary vaccine dose or 4 days before 2 months [or more than 4 days before 8 weeks] after a Janssen primary vaccine dose), the booster dose does **not** need to be repeated.

mRNA primary series recipients: People aged 18 years and older who received an mRNA primary series (including people who received two doses of different mRNA COVID-19 vaccine products for their primary series) should receive a single COVID-19 booster dose (Pfizer-BioNTech, Moderna, or Janssen) at least 6 months after completion of the primary series. Moderately or severely immunocompromised people aged ≥ 18 years who received a 2-dose mRNA primary series and an additional primary dose should receive a single COVID-19 booster dose (Pfizer-BioNTech, Moderna, or Janssen) at least 6 months after completing their third mRNA vaccine dose.

Janssen primary series recipients: People aged 18 years and older who received a single dose of Janssen COVID-19 vaccine should receive a single COVID-19 booster dose (Pfizer-BioNTech, Moderna, or Janssen) at least 2 months (8 weeks) after completing their Janssen primary series.

Dosing

The following vaccine-specific booster dose and volume should be administered regardless of whether the vaccine is homologous (same dose as primary series) or heterologous (different than primary series).

- Pfizer-BioNTech: 30 μg in a volume of 0.3 mL (same dose as the primary series dose and additional primary dose)
- Moderna: 50 μg in a volume of 0.25 mL. **This is a different dose than what is used for the primary series dose and the additional primary dose.**
- Janssen: 5×10^{10} viral particles in a volume of 0.5 mL (same dose as the primary series dose)

TABLE 2. COVID-19 vaccines: booster dose

Vaccine manufacturer	Age indication, years	Vial cap color denoting formulation	Dose	Injection volume	Number of doses	Interval between last primary (including additional) dose to booster dose
Pfizer-BioNTech	≥ 18	Purple	30 μg	0.3 mL	1	≥ 6 months
Moderna	≥ 18	Not applicable	50 μg	0.25 mL	1	≥ 6 months
Janssen	≥ 18	Not applicable	5×10^{10} viral particles	0.5 mL	1	≥ 2 months

Source: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#vaccinated-part-clinical-trail>, Accessed November 30, 2021

Update 2: People who were vaccinated outside the United States with a currently FDA-approved or FDA-authorized COVID-19 vaccine:

- If they received all of the recommended doses of a single dose or 2-dose primary COVID-19 vaccine series, they are considered [fully vaccinated](#). People who are moderately or severely immunocompromised and were vaccinated with a 2-dose mRNA COVID-19 vaccine primary series should receive an additional primary dose as detailed in [Considerations for COVID-19 vaccination in moderately or severely immunocompromised people](#). People vaccinated with an FDA-approved or FDA-authorized COVID-19 vaccine outside the United States should also follow guidance for booster doses as detailed in the [Booster dose](#) section.
- If they received the first dose of a 2-dose mRNA COVID-19 vaccine series, they **do not need to restart** the vaccine series in the United States. They should receive the second dose as close to the recommended time as possible and are considered fully vaccinated upon completion of the 2-dose primary series. This also applies to people who were vaccinated in countries where only a single mRNA dose is administered; they are not considered [fully vaccinated](#) in the United States until after completion of the 2-dose series.

People who completed all of the recommended doses of an WHO-EUL COVID-19 vaccine⁴ not approved or authorized by FDA (refer to list of WHO-EUL COVID-19 vaccines), or people who completed a heterologous (mix and match) series composed of any combination of FDA-approved, FDA-authorized, or WHO-EUL COVID-19 vaccines:

- Are considered [fully vaccinated](#).
- Under the [EUI](#), moderately or severely immunocompromised people aged ≥ 12 years should receive an additional primary dose of Pfizer-BioNTech COVID-19 Vaccine (30 μg formulation [purple cap]) at least 28 days after receiving the second vaccine dose of their primary series as detailed in [Considerations for COVID-19 vaccination in moderately or severely immunocompromised people](#).
- Under the [EUI](#), people aged ≥ 18 years (including moderately or severely immunocompromised people who received an additional primary dose) should receive a single booster dose of Pfizer-BioNTech COVID-19 Vaccine (30 μg formulation [purple cap]) at least 6 months after completing their primary series, as detailed in the [Booster dose](#) section.

People who received only the first dose of a multidose WHO-EUL COVID-19 primary series⁴ that is not FDA-approved or FDA-authorized, or who received all or some of the recommended doses of a COVID-19 vaccine primary series that is not listed for emergency use by WHO:

- Should be offered primary vaccination with an FDA-approved or FDA-authorized COVID-19 vaccine (i.e., 2-dose mRNA series or single Janssen dose), with a minimum interval of at least 28 days since receipt of the last dose of a non-FDA-approved/authorized vaccine.
- After completion of primary vaccination with an FDA-approved or FDA-authorized COVID-19 vaccine, these individuals are considered fully vaccinated, and are not recommended to receive an additional primary or booster dose at this time.

Source: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>, Accessed November 30, 2021

Vaccinated Outside the United States?

You're fully vaccinated if you have received one dose of Johnson and Johnson's Janssen vaccine or ANY combination of two doses of an FDA approved/authorized or WHO listed vaccines.

Vaccine	Age	Doses	FDA Authorized	FDA Approved	WHO Listed
Pfizer-BioNTech ¹	12-15	2	✓		
Pfizer-BioNTech (COMIRNATY)	16+	2		✓	✓
Moderna	18+	2	✓		✓
Johnson and Johnson's Janssen ²	18+	1	✓		✓
AstraZeneca ³	18+	2			✓
Sinopharm BIBP	18+	2			✓
Sinovac-CoronaVac	18+	2			✓



1. Labeled as COMIRNATY in European Union

2. Labeled as Janssen-Cilag in European Union

3. Labeled as COVISHIELD in Canada and others, labeled as AstraZeneca/SKBio in Republic of Korea



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Update 3: People who received COVID-19 vaccine as part of a clinical trial

Participants in clinical trials within or outside the United States who received all of the recommended “active” (not placebo) primary series doses of a WHO-EUL COVID-19 vaccine⁴ that is not FDA-approved or FDA-authorized or a vaccine that is not listed for emergency use by WHO⁴ but for which a U.S. data and safety monitoring board or equivalent has independently confirmed efficacy (i.e., Novavax COVID-19 Vaccine, Moderna COVID-19 Vaccine in children aged 6-17 years):

- Are considered [fully vaccinated](#).
- Unless they have received or plan to receive an additional dose through a clinical trial, under [EUI](#), moderately or severely immunocompromised clinical trial participants aged ≥12 years should receive an additional primary dose of Pfizer-BioNTech COVID-19 Vaccine (30 µg formulation [purple cap]) at least 28 days after receiving the second vaccine dose of their primary series as detailed in the [Considerations for COVID-19 vaccination in moderately or severely immunocompromised people](#).
- Unless they have received or plan to receive a booster dose through a clinical trial, under [EUI](#), clinical trial participants aged ≥18 years (including moderately or severely immunocompromised people who received an additional primary dose) should receive a single booster dose of Pfizer-BioNTech COVID-19 Vaccine (30 µg formulation [purple cap]) at least 6 months after completing their primary series, as detailed in the [Booster dose](#) section.
- If clinical trial participants have questions about whether they should receive an additional and/or booster dose outside of the clinical trial, they should consult with their healthcare provider.

Clinical trial participants who did not receive all of the recommended doses, or who received other vaccines not listed above, should consult with their healthcare provider to determine if they should receive an FDA-approved or FDA-authorized COVID-19 vaccine series.

Links to other Information and Resources

- CDC: [Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States](#)
- FDA Fact Sheets for Healthcare Providers Administering Vaccine
 - [Pfizer \(for age 5 through 11\)](#) (10/29/21)
 - [Pfizer \(for age 12 years and older\)](#) (11/19/21)
 - [Moderna](#) (11/19/21)
 - [Janssen \(Johnson & Johnson\)](#) (11/19/21)
- FDA Fact Sheets for Recipients and Caregivers
 - [Pfizer \(for age 5 through 11\)](#) (10/29/2021)
 - [Pfizer \(for age 12 years and older\)](#) (11/19/21)
 - [Moderna](#) (11/19/21)
 - [Janssen \(Johnson & Johnson\)](#) (11/19/21)

- [ACIP main page](#) for content from previous meetings, as well as information about future meetings
- CDC: [ACIP Presentation Slides: November 19, 2021 Meeting](#) web page
- CDC: [CDC Expands Eligibility for COVID-19 Booster Shots to All Adults](#)

Source: Immunization Action Coalition. *IAC Express*. Issue No. 1601. November 24, 2021.