Centers for Disease Control and Prevention

Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States

The Advisory Committee on Immunization Practices will be meeting to discuss recommendations for the recently authorized Moderna COVID-19 Vaccine for ages 6-17 years on June 23rd. The Interim Clinical Considerations and associated materials for healthcare providers will be updated with applicable guidance soon after that meeting.

Summary of recent changes (last updated June 19, 2022):

- New guidance for use of Pfizer-BioNTech COVID-19 Vaccine in children ages 6 months–4 years
- New guidance for use of Moderna COVID-19 Vaccine in children ages 6 months–5 years
- Reorganization of sections on COVID-19 vaccination recommendations and schedules
- Addition of new section in Special populations for infants and young children

Reference Materials

- Summary Document for Interim Clinical Considerations
- Interim COVID-19 Immunization Schedule
- At-A-Glance COVID-19 Vaccination Schedule (NEW 6/19/2022)

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What's this?

About the clinical considerations

Key points

- COVID-19 vaccines currently approved or authorized by FDA are effective in preventing serious outcomes of coronavirus disease 2019 (COVID-19), including severe disease, hospitalization, and death.
- Everyone ages 6 months and older in the United States should receive a COVID-19 primary series vaccination for the prevention of COVID-19.
- Everyone ages 5 years and older should receive at least 1 booster dose of COVID-19 vaccine if eligible (i.e., if a booster dose is FDA-approved or FDA-authorized for use in a specified population). Recommendations for booster dose(s) vary based on age, COVID-19 vaccine product, and immunocompetence.
- Janssen COVID-19 Vaccine should only be used in limited situations; Pfizer-BioNTech or Moderna COVID-19 Vaccines are preferred for primary and booster vaccination.
- Efforts to increase the number of people in the United States who are up to date with their COVID-19 vaccines remain critical to preventing illness, hospitalizations, and deaths from COVID-19.
- These clinical considerations provide additional information to healthcare professionals and public health officials on use of COVID-19 vaccines.

Purpose

The Centers for Disease Control and Prevention (CDC) Interim Clinical Considerations provides additional information to healthcare professionals and public health officials on the use of COVID-19 vaccines. They are informed by the Advisory Committee on Immunization Practices (ACIP) and CDC's recommendations, data submitted to the U.S. Food and Drug Administration (FDA) for Biologics License Application (BLA) or Emergency Use Authorization (EUA) of the vaccines, Emergency Use Instructions (EUI) for FDA-approved vaccines, other data sources, including the World Health Organization (WHO) emergency use listing (EUL) evaluation of COVID-19 vaccines and clinical trial results, general best practice guidelines for immunization, and expert opinion (Box 1).

These considerations apply only to the use of vaccine products currently approved or authorized in the United States. These considerations will be updated when additional information becomes available or if additional vaccine products are approved or authorized.

Overview of COVID-19 vaccination

COVID-19 vaccines

Three COVID-19 vaccines are currently approved under a Biologics License Application (BLA) or authorized under an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA) (Table 1) (Box 1):

- Pfizer-BioNTech COVID-19 Vaccine/COMIRNATY (hereafter referred to as Pfizer-BioNTech in this document) *(1)*
- Moderna COVID-19 Vaccine/SPIKEVAX (hereafter referred to as Moderna in this document) *(2)*
- Janssen (Johnson & Johnson) COVID-19 Vaccine (hereafter referred to as Janssen in this document)

The Pfizer-BioNTech and Moderna vaccines are lipid nanoparticle-formulated, nucleoside-modified mRNA vaccines encoding the prefusion spike glycoprotein of SARS-CoV-2, the virus that causes COVID-19. The Janssen COVID-19 Vaccine is a recombinant, replication-incompetent adenovirus type 26 (Ad26) vector encoding the stabilized prefusion spike glycoprotein of SARS-CoV-2. None of the currently FDA-approved or FDA-authorized COVID-19 vaccines are live-virus vaccines.

Box 1. Regulatory terminology for COVID-19 vaccines

Emergency Use Authorization **(EUA):** Mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. Under an EUA, the U.S. Food and Drug Administration (FDA) can make a product available to the public based on the best available evidence, without waiting for all the evidence that would be needed for FDA approval.

FDA Approved **:** FDA-approved vaccines have undergone the agency's standard process for reviewing the quality, safety and effectiveness of medical products included in a manufacturer's submission of a Biologics License Application **(BLA)**—a comprehensive document that addresses specific requirements.

Emergency Use Instructions **(EUI):** Provision of the 2013 Pandemic and All-Hazards Preparedness Reauthorization Act which gives CDC legal authority to create and issue EUI to permit emergency use of FDA-approved medical products. The EUI consist of Fact Sheets to inform healthcare providers and recipients about approved, licensed, or cleared conditions of use, and may provide information about emergency use of FDA-approved medical products that is not included in or differs in some way from the information provided in the FDA-approved labeling (package insert).

For primary and booster vaccination for all populations, an mRNA COVID-19 vaccine (i.e., Pfizer-BioNTech or Moderna) is preferred over the Janssen COVID-19 Vaccine; Janssen vaccine cannot be used for the second booster dose.

Janssen COVID-19 Vaccine is authorized for adults ages 18 years and older and should only be used in limited situations due to the risk of thrombosis with thrombocytopenia syndrome (TTS) following receipt of the Janssen COVID-19 Vaccine (see Patient counseling and Safety considerations for Janssen COVID-19 Vaccine). However, offering the Janssen COVID-19 Vaccine is preferable to not providing any COVID-19 vaccine.

COVID-19 vaccine-specific FDA fact sheets and U.S. COVID-19 Vaccine Product Information can be consulted for a full list of ingredients and additional information on the conditions of use, storage and handling, preparation, and administration procedures for each of the FDA-approved and FDA-authorized COVID-19 vaccine products.

Groups recommended for vaccination

COVID-19 vaccination is recommended for everyone ages 6 months and older in the United States for the prevention of COVID-19. CDC recommends that people get up to date with COVID-19 vaccination as soon as feasible.

There is currently no FDA-approved or FDA-authorized COVID-19 vaccine for children younger than 6 months. These children should not receive any COVID-19 vaccine doses (including partial doses of vaccine products approved or authorized for people ages 6 months and older) at this time unless part of a clinical trial.

Vaccination schedule

The recommended schedule and use of each COVID-19 vaccine product approved under BLA or authorized under EUA varies by the age and immune status of the recipient. There are two vaccination schedules: one for people who are not moderately or severely immunocompromised and one for people who are moderately or severely immunocompromised.

Vaccination providers should ensure the correct age-appropriate product is administered based on the recipient's age on the day of vaccination (Table 1). Vaccine doses should be administered by the intramuscular route and in accordance with the recommended intervals for that age group *(3)*. For guidance on timing of vaccination in specific situations, see Transitioning from a younger to older age group, Considerations for intervals for mRNA vaccines, and COVID-19 vaccination and SARS-CoV-2-infection.

COVID-19 vaccine use terminology, including primary series and booster dose vaccination and up to date, is defined in Box 2.

See Appendices A (People who received COVID-19 vaccine outside the United States) and B (People who received COVID-19 Vaccine as part of a clinical trial) for recommendations for these populations.

Table 1. COVID-19 vaccine products currently approved or authorized in the United States*

Pfizer-BioNTech

Age indication	Vaccine vial cap color	Label border color	Dilution required	Primary series		Booster doses†	
				Dose	Injection volume	Dose	Injection volume
6 months–4 years‡	Maroon	Maroon	Yes	3 µg	0.2 mL	NA	NA
5–11 years	Orange	Orange	Yes	10 µg	0.2 mL	10 µg	0.2 mL
12 years and older	Purple	Purple	Yes	30 µg	0.3 mL	30 µg	0.3 mL
12 years and older	Gray	Gray	No	30 µg	0.3 mL	30 µg	0.3 mL

Moderna

Age indication	Vaccine vial cap color	Label border color	Dilution required	Primary series		Booster doses†	
				Dose	Injection volume	Dose	Injection volume
6 months–5 years	Dark blue	Magenta	No	25 µg	0.25 mL	NA	NA
18 years and older	Red	Light blue	No	100 µg	0.5 mL	50 µg	0.25 mL
18 years and older	Dark blue	Purple	No	NA	NA	50 µg	0.5 mL

Janssen

Age indication	Vaccine vial cap color	Label border color	Dilution required	Primary series		Booster doses†	
				Dose	Injection volume	Dose	Injection volume
18 years and older	Blue	Purple	No	5×10^{10} viral particles	0.5 mL	5×10^{10} viral particles	0.5 mL

Abbreviation: NA = not authorized

* Product-specific information is available from FDA for Pfizer-BioNTech and Moderna COVID-19 vaccines and from CDC for all FDA-authorized or -approved vaccines.

†For people ages 5–17 years, Pfizer-BioNTech COVID-19 Vaccine is currently FDA-authorized for use as a booster dose in people who received Pfizer-BioNTech as their primary series; Moderna COVID-19 Vaccine is not authorized for use as a booster dose in this age group. For people ages 18 years and older, Pfizer-BioNTech and Moderna can be used as a booster dose.

‡Vials of the Pfizer-BioNTech COVID-19 Vaccine with a maroon vial cap and maroon label border may state "Age 2y to < 5y" or "Age 6m to <5 yr." Carton labels may state "For age 2 years to <5 years" or "For age 6 months to <5 years." Vials with either printed age range can be used for children ages 6 months-4 years.

Box 2. Terminology for COVID-19 vaccine use

Primary series: Initial vaccination which can range from a single dose to a 3-dose series depending on the vaccine product and a person's age and immune status.

Additional dose: A dose of vaccine administered after the primary series to people who are less likely to mount a protective immune response after initial vaccination. People who are moderately or severely immunocompromised and who received Janssen COVID-19 Vaccine for their primary series should receive an additional dose.

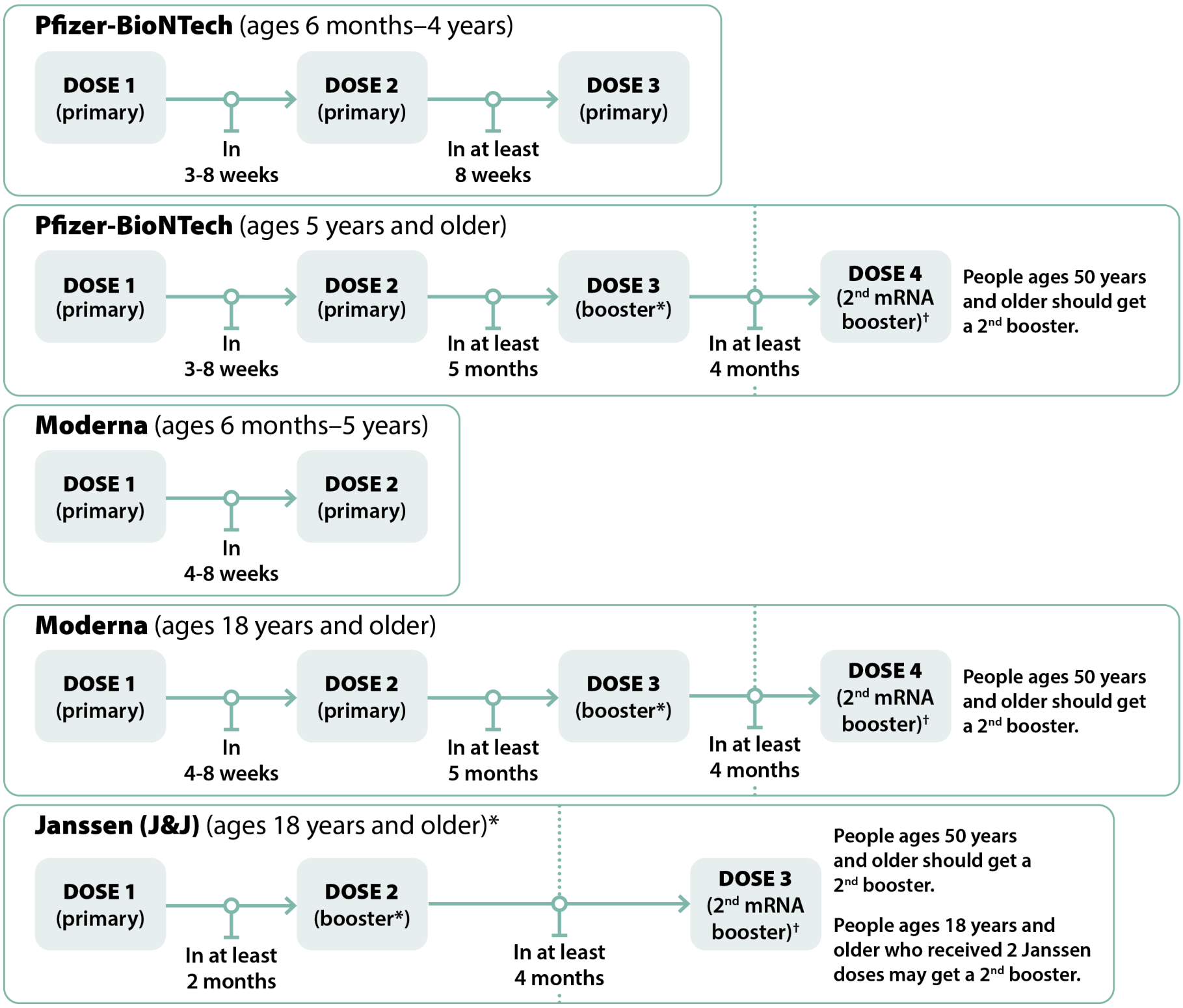
Booster dose: A subsequent dose of vaccine administered to enhance or restore protection which might have waned over time after primary series vaccination.

- **Homologous booster dose:** The same vaccine product used for the booster dose was administered for the primary series.
- **Heterologous booster dose (mix-and-match booster):** The vaccine product used for the booster dose differs from the product administered for the primary series.

Up to date**:** People ages 6 months and older are up to date with their COVID-19 vaccines when they have received all doses in the primary series and all booster doses recommended for them, when eligible.

COVID-19 vaccination guidance for people who are **not** moderately or severely immunocompromised

Overview



*Age-appropriate mRNA COVID-19 vaccines are preferred over Janssen COVID-19 Vaccine for primary and booster vaccination. Janssen COVID-19 Vaccine should only be used in limited situations. See: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#considerations-Janssen

†2nd booster dose for some groups

View the COVID-19 Vaccination Schedule for Most People

For primary series and booster dose(s), an age-appropriate mRNA COVID-19 vaccine (i.e., Pfizer-BioNTech or Moderna) is preferred over the Janssen COVID-19 Vaccine. The same mRNA vaccine product should be used for all doses of the primary series (see Interchangeability of COVID-19 vaccine products). All people ages 5 years and older should receive at least 1 booster dose if eligible (i.e., if a booster dose is FDA-approved or FDA-authorized for use in a specified population); an mRNA vaccine must be used for the second booster dose.

Information about age-specific vaccine products and dosages can be found in Table 1.

Table 2. COVID-19 vaccination schedule for people who are NOT moderately or severely immunocompromised

6 months through 11 years

Manufacturer*	Age group	Total number of doses recommended	Number of primary doses	Number of booster doses	Interval between 1st and 2nd dose†	Interval between 2nd and 3rd dose	Interval between 3rd and 4th dose
Pfizer-BioNTech	6 months–4 years	3	3	NA	3-8 weeks	At least 8 weeks	NA
Pfizer-BioNTech	5–11 years	3	2	1	3-8 weeks	At least 5 months	NA
Moderna	6 months–5	2	2	NA	4-8 weeks	NA	NA

	years						

12 through 17 years

Manufacturer*	Age group	Total number of doses recommended	Number of primary doses	Number of booster doses	Interval between 1st and 2nd dose†	Interval between 2nd and 3rd dose	Interval between 3rd and 4th dose
Pfizer-BioNTech	12–17 years	3	2	1	3-8 weeks	At least 5 months	NA

18 years and older

Manufacturer*	Age group	Total number of doses recommended	Number of primary doses	Number of booster doses	Interval between 1st and 2nd dose†	Interval between 2nd and 3rd dose	Interval between 3rd and 4th dose
Pfizer-BioNTech	18–49 years	3	2	1	3-8 weeks	At least 5 months	NA
Pfizer-BioNTech	50 years and older	4	2	2	3-8 weeks	At least 5 months	At least 4 months
Moderna	18–49 years	3	2	1	4-8 weeks	At least 5 months	NA
Moderna	50 years and older	4	2	2	4-8 weeks	At least 5 months	At least 4 months
Janssen	18–49 years	2	1	1‡	At least 2 months	NA	NA
Janssen	50 years and older	3	1	2	At least 2 months	At least 4 months	NA

Abbreviations: NA = not authorized

* mRNA COVID-19 vaccines are preferred over Janssen COVID-19 Vaccine for both primary and booster doses; an mRNA COVID-19 vaccine must be used for the second booster dose.

†An **8-week** interval may be optimal for some people ages 6 months–64 years, especially for males ages 12–39 years. A **shorter interval** (3 weeks for Pfizer-BioNTech; 4 weeks for Moderna) between the first and second doses remains the recommended interval for people who are moderately or severely immunocompromised; adults ages 65 years and older; and in situations in which there is increased concern about COVID-19 community levels or an individual's higher risk of severe disease.

‡People ages 18–49 who received Janssen COVID-19 Vaccine as both their primary dose and first booster dose may receive a second booster dose using an mRNA vaccine at least 4 months after the first booster dose.

Schedule: ages 6 months through 11 years

Pfizer-BioNTech COVID-19 Vaccine

- Children ages 6 months–4 years: Should receive a 3-dose primary series. The first and second doses are separated by 3-8 weeks and the second and third doses are separated by at least 8 weeks. Currently, a booster is not authorized for this age group.
- Children ages 5–11 years: Should receive a 2-dose primary series separated by 3-8 weeks and 1 booster dose at least 5 months after completion of the primary series.

Moderna COVID-19 Vaccine

- Children ages 6 months–5 years: Should receive a 2-dose primary series separated by 4-8 weeks. Currently, a booster dose is not authorized for children in this age group who receive a Moderna primary series.

Schedule: ages 12 through17 years

Pfizer-BioNTech COVID-19 Vaccine

- Adolescents ages 12–17 years: Should receive a 2-dose primary series separated by 3-8 weeks and 1 booster dose at least 5 months after completion of the primary series.

Schedule: ages 18 years and older

Pfizer-BioNTech COVID-19 Vaccine

- Adults ages 18–49 years: Should receive a 2-dose primary series separated by 3-8 weeks and 1 booster dose at least 5 months after completion of the primary series.
- Adults ages 50 years and older: Should receive a 2-dose primary series separated by 3-8 weeks and 2 booster doses. The first booster dose should be administered at least 5 months after completion of the primary series and the second booster dose at least 4 months after the first booster dose.

Moderna COVID-19 Vaccine

- Adults ages 18–49 years: Should receive a 2-dose primary series separated by 4-8 weeks and 1 booster dose at least 5 months after completion of the primary series.
- Adults ages 50 years and older: Should receive a 2-dose primary series separated by 4-8 weeks and 2 booster doses. The first booster dose should be administered at least 5 months after completion of the primary series and the second booster dose at least 4 months after the first booster dose.

Janssen COVID-19 Vaccine

Janssen COVID-19 Vaccine should only be used in limited situations and cannot be used as a second booster; see Contraindications and precautions and Safety considerations for Janssen COVID-19 Vaccine.

- Adults ages 18–49 years: Should receive 1 primary dose and 1 booster dose at least 2 months after the primary dose. In addition, people who received Janssen COVID-19 Vaccine as both their primary series dose and first booster dose may receive a second booster dose at least 4 months after the first booster dose, for a total of 3 doses.
- Adults ages 50 years and older: Should receive 1 primary dose and 2 booster doses. The first booster dose should be administered at least 2 months after the primary dose and the second booster dose at least 4 months after the first booster dose.

Considerations for intervals for mRNA COVID-19 vaccine primary series

mRNA COVID-19 vaccines are FDA-approved or FDA-authorized for a 3-week (Pfizer-BioNTech vaccine) or 4-week (Moderna vaccine) interval between the first and second dose. A 3- or 4-week interval continues to be the recommended interval for people who are moderately or severely immunocompromised, adults ages 65 years and older, and in situations when the fullest possible protection needs to be achieved sooner (e.g., increased concern about COVID-19 community levels or an individual's higher risk for severe disease).

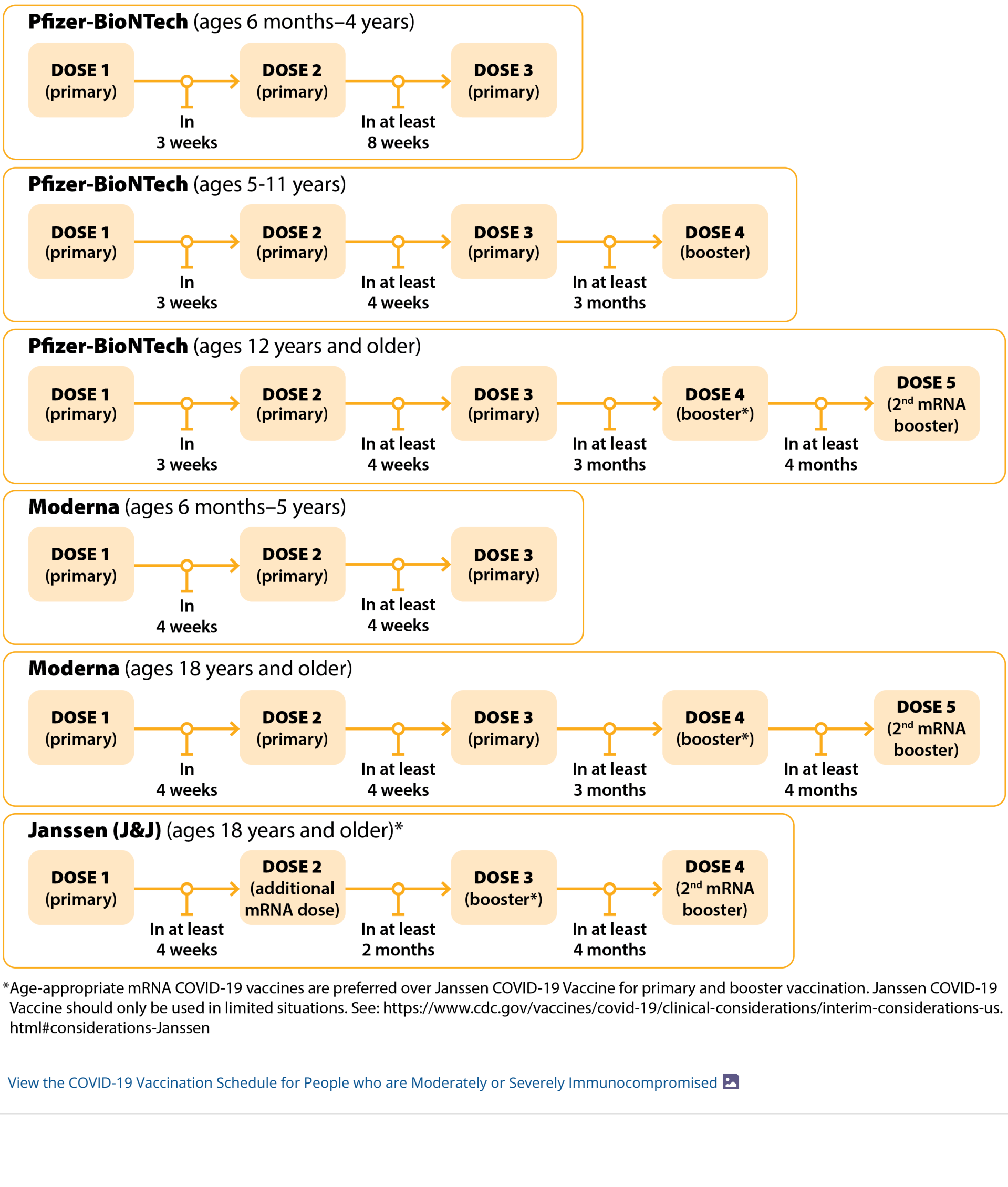
mRNA COVID-19 vaccines are safe and effective at the FDA-approved or FDA-authorized intervals, but a longer interval may be considered for some populations. While absolute risk remains small, the risk for myocarditis is higher for males ages 12-39 years, and this risk might be reduced by extending the interval between the first and second dose. Some studies in adolescents (ages 12-17 years) and adults have shown the small risk of myocarditis associated with mRNA COVID-19 vaccines might be reduced and peak antibody responses and vaccine effectiveness may be increased with an interval longer than 4 weeks. Extending the interval beyond 8 weeks has not been shown to provide additional benefit. **In summary, an 8-week interval may be optimal for people who are not moderately or severely immunocompromised and ages 6 months-64 years, especially for males ages 12–39 years.**

COVID-19 vaccination guidance for people who are moderately or severely immunocompromised

People with immunocompromising conditions or people who take immunosuppressive medications or therapies are at increased risk for severe COVID-19. Because the immune response following COVID-19 vaccination may differ in people who are moderately or severely immunocompromised at the time of vaccination, specific guidance for this population is provided.

In addition to COVID-19 vaccination, providers should consult current treatment guidelines for use of monoclonal antibodies as pre-exposure prophylaxis (tixagevimab/cilgavimab [EVUSHELD™]) for people who are moderately or severely immunocompromised and who may be less likely to mount a protective immune response to COVID-19 vaccination. Such use of monoclonal antibodies, however, is not a substitute for COVID-19 vaccination. See the section on COVID-19 vaccination and SARS-CoV-2 infection for information on timing of administration of tixagevimab/cilgavimab (EVUSHELD™) in relation to COVID-19 vaccination.

Overview



*Age-appropriate mRNA COVID-19 vaccines are preferred over Janssen COVID-19 Vaccine for primary and booster vaccination. Janssen COVID-19 Vaccine should only be used in limited situations. See: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#considerations-Janssen

View the COVID-19 Vaccination Schedule for People who are Moderately or Severely Immunocompromised

For primary series and booster doses(s), an age-appropriate mRNA COVID-19 vaccine (i.e., Pfizer-BioNTech or Moderna) is preferred over the Janssen COVID-19 Vaccine. The same mRNA vaccine product should be used for all doses of the primary series (see Interchangeability of COVID-19 vaccine products). All people ages 5 years and older should receive at least 1 booster dose if eligible; an mRNA vaccine must be used for the second booster dose.

Information about age-specific vaccine products and dosages can be found in Table 1.

People who are or who become moderately or severely immunocompromised should follow the COVID-19 vaccination schedule according to their age and immune status at the time of eligibility for doses. For example, people who become moderately or severely immunocompromised after completing a 2-dose mRNA or single-dose Janssen COVID-19 Vaccine primary series do not need additional primary doses; however, they should follow the schedule for people who are moderately or severely immunocompromised for booster doses. For situations in which diminished vaccine efficacy is anticipated, see Additional considerations for vaccination outside of the FDA and CDC dosing intervals on a case-by-case basis.

Table 3. COVID-19 vaccination schedule for people who are moderately or severely immunocompromised

Ages 6 months through 11 years

Manufacturer*	Age group	Total number of doses recommended	Number of primary doses	Number of booster doses	Interval between 1st and 2nd dose	Interval between 2nd and 3rd dose	Interval between 3rd and 4th dose	Interval between 4th and 5th dose
Pfizer-BioNTech	6 months–4 years	3	3	NA	3 weeks	At least 8 weeks	NA	NA
Pfizer-BioNTech	5–11 years	4	3	1	3 weeks	At least 4 weeks	At least 3 months	NA
Moderna	6 months–5 years	3	3	NA	4 weeks	At least 4 weeks	NA	NA

12 through 17 years

Manufacturer*	Age group	Total number of doses recommended	Number of primary doses	Number of booster doses	Interval between 1st and 2nd dose	Interval between 2nd and 3rd dose	Interval between 3rd and 4th dose	Interval between 4th and 5th dose
Pfizer-BioNTech	12–17 years	5	3	2	3 weeks	At least 4 weeks	At least 3 months	At least 4 months

18 years and older

Manufacturer*	Age group	Total number of doses recommended	Number of primary doses	Number of booster doses	Interval between 1st and 2nd dose	Interval between 2nd and 3rd dose	Interval between 3rd and 4th dose	Interval between 4th and 5th dose
Pfizer-BioNTech	18 years and older	5	3	2	3 weeks	At least 4 weeks	At least 3 months	At least 4 months
Moderna	18 years and older	5	3	2	4 weeks	At least 4 weeks	At least 3 months	At least 4 months
Janssen	18 years and older	4	2 (1 Janssen, followed by 1 mRNA)	2	4 weeks	At least 2 months	At least 4 months	NA

Abbreviation: NA = not authorized

*mRNA COVID-19 vaccines are preferred over Janssen COVID-19 Vaccine for both primary and booster doses; an mRNA COVID-19 vaccine must be used for the second booster dose.

Schedule: ages 6 months through 11 years

Pfizer-BioNTech COVID-19 Vaccine

- Children ages 6 months–4 years: Should receive a 3-dose primary series. The first and second doses are separated by 3 weeks and the second and third doses are separated by at least 8 weeks. Currently, a booster dose is not authorized for this age group.
- Children ages 5–11 years: Should receive a 3-dose primary series and 1 booster dose. For the primary series, the first and second doses are separated by 3 weeks and the second and third doses are separated by at least 4 weeks. The booster dose is administered at least 3 months after completion of the primary series.

Moderna COVID-19 Vaccine

- Children ages 6 months–5 years: Should receive a 3-dose primary series. The first and second doses are separated by 4 weeks and the second and third doses are separated by at least 4 weeks. Currently, a booster dose is not authorized for children in this age group who receive a Moderna primary series.

Schedule: ages 12 through 17 years

Pfizer-BioNTech COVID-19 Vaccine

- Adolescents ages 12–17 years: Should receive a 3-dose primary series and 2 booster doses. For the primary series, the first and second doses are separated by 3 weeks and the second and third doses are separated by at least 4 weeks. The first booster dose is administered at least 3 months after completion of the primary series and the second booster dose at least 4 months after the first booster dose.

Schedule: ages 18 years and older

Pfizer-BioNTech COVID-19 Vaccine

- Adults ages 18 years and older: Should receive a 3-dose primary series and 2 booster doses. For the primary series, the first and second doses are separated by 3 weeks and the second and third doses are separated by at least 4 weeks. The first booster dose is administered at least 3 months after completion of the primary series and the second booster dose at least 4 months after the first booster dose.

Moderna COVID-19 Vaccine

- Adults ages 18 years and older: Should receive a 3-dose primary series and 2 booster doses. For the primary series, the first and second doses are separated by 4 weeks and the second and third doses are separated by at least 4 weeks. The first booster dose is administered at least 3 months after completion of the primary series and the second at least 4 months after the first booster dose.

Special situation: For people who inadvertently received the booster dose before their third primary dose, regardless of type of vaccine received as the booster dose, administer a Pfizer-BioNTech vaccine or a Moderna vaccine as the fourth dose (third primary) at least 3 months after the third dose. See Appendix D for additional guidance.

Janssen COVID-19 Vaccine

Janssen COVID-19 Vaccine should only be used in limited situations and cannot be used as a second booster; see Contraindications and precautions and Safety considerations for Janssen COVID-19 Vaccine.

- Adults ages 18 years and older: Should receive 1 primary dose, a second (additional) dose using an mRNA COVID-19 vaccine, and 2 booster doses. The primary series dose and the additional dose are separated by at least 4 weeks. The first booster dose is administered at least 2 months after the additional dose and the second booster dose at least 4 months after the first booster dose.

Special situation: Many recipients of Janssen COVID-19 Vaccine may have received a booster dose (Pfizer-BioNTech, Moderna [50 µg], or Janssen vaccine), without having had the second (additional) mRNA vaccine dose. In this situation, regardless of type and timing of vaccine received as the second dose, administer a Pfizer-BioNTech vaccine or a Moderna vaccine as the third (additional) dose at least 2 months after dose 2. See Appendix D for additional dose information for Janssen COVID-19 Vaccine recipients.

Description of moderate and severe immunocompromising conditions and treatment

Moderate and severe immunocompromising conditions and treatments include but are not limited to:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic cell transplant (HCT) (within 2 years of transplantation or taking immunosuppressive therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts less than 200/mm^3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (i.e., 20 or more mg of prednisone or equivalent per day when administered for 2 or more weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory

Factors to consider in assessing the general level of immune competence in a patient include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment. Age or place of residence alone (e.g., residence in a long-term care setting), independent of a patient's medical condition, should not be used to determine the level of immune competence.

For additional information about the degree of immune suppression associated with different medical conditions and treatments, providers can consult ACIP's general best practices for vaccination of people with altered immunocompetence, the CDC Yellow Book, and the Infectious Diseases Society of America policy statement, 2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host .

Considerations for COVID-19 revaccination

Revaccination is defined as repeating 1 or more dose(s) of vaccine. COVID-19 revaccination should be with an mRNA vaccine (Table 3) regardless of vaccine administered for initial vaccination. Recipients of HCT or CAR-T-cell therapy who received one or more doses of COVID-19 vaccine prior to or during treatment should undergo revaccination for any dose(s) received before and during treatment. Revaccination should start at least 3 months (12 weeks) after transplant or CAR-T-cell therapy.

Revaccination may also be considered for patients who received 1 or more doses of COVID-19 vaccine during treatment with B-cell-depleting therapies (e.g., rituximab, ocrelizumab) that were administered over a limited period (e.g., as part of a treatment regimen for certain malignancies). The suggested interval to start revaccination is about 6 months after completion of the B-cell-depleting therapy. Timing of vaccination for patients who receive B-cell-depleting therapies on a continuing basis (e.g., for treatment of certain autoimmune conditions such as rheumatoid arthritis or multiple sclerosis) is addressed in Considerations for timing of COVID-19 vaccination in relation to immunosuppressive therapies.

A patient's clinical team is best positioned to determine the degree of immune compromise, need for revaccination, appropriate timing of revaccination, and potential use of EVUSHELD™.

Considerations for timing of COVID-19 vaccination in relation to immunosuppressive therapies

Administration of COVID-19 vaccines should not be delayed in patients taking immunosuppressive therapies. Whenever possible, COVID-19 vaccines should be administered at least 2 weeks before initiation or resumption of immunosuppressive therapies. For patients who receive B-cell-depleting therapies on a continuing basis, COVID-19 vaccines should be administered approximately 4 weeks before the next scheduled therapy.

Timing of COVID-19 vaccination should take into consideration current or planned immunosuppressive therapies, optimization of both the patient's medical condition and anticipated response to vaccination, and individual benefits and risks.

The utility of serologic testing , cellular immune testing, or B-cell quantification to assess immune response to vaccination and guide clinical care has not been established. Such testing outside of the context of research studies is not recommended at this time.

Self-attestation of immunocompromised status

People can self-attest to their moderately or severely immunocompromised status and receive COVID-19 vaccine doses wherever vaccines are offered. Vaccinators should not deny COVID-19 vaccination to a person due to lack of documentation.

Additional considerations

On a case-by-case basis, providers caring for moderately or severely immunocompromised patients may administer mRNA COVID-19 vaccines outside of the FDA and CDC dosing intervals based on clinical judgment when the benefits of vaccination are deemed to outweigh the potential and unknown risks for the recipient. However, providers should not routinely administer doses of COVID-19 vaccine beyond those recommended in this guidance.

Vaccinated people who are moderately or severely immunocompromised should be counseled about the potential for a reduced immune response to COVID-19 vaccines. They and their close contacts should continue to follow current prevention measures.

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Timing, spacing, and interchangeability of COVID-19 vaccines

The following considerations related to the timing, spacing, and interchangeability of COVID-19 vaccines apply to the recommendations and schedules for people who are **not** moderately or severely immunocompromised and people who are moderately or severely immunocompromised.

4-Day grace period

Doses administered up to 4 days before the minimum interval, known as the 4-day grace period, are considered valid. This applies to primary series and booster doses. If a dose is administered prior to the 4-day grace period, see Appendix C. Doses administered at any time after the recommended interval are valid.

Interchangeability of COVID-19 vaccine products

In general, the same mRNA vaccine product should be used for all doses in the primary series.

In exceptional situations in which the mRNA vaccine product administered for a previous dose(s) of the primary series cannot be determined or is not available, any age-appropriate mRNA COVID-19 vaccine product may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 primary vaccination series.

Children ages 6 months–4 years who receive different mRNA products for the first 2 doses of an mRNA COVID-19 vaccine series should follow a 3-dose schedule. A third dose of either mRNA vaccine should be administered at least 8 weeks after the second dose to complete the 3-dose primary series.

In exceptional situations where a person received the first dose of an mRNA COVID-19 vaccine but is unable to complete the series with either the same or different mRNA COVID-19 vaccine (e.g., due to a contraindication), a single dose of Janssen COVID-19 Vaccine may be considered at a minimum interval of 28 days from the mRNA COVID-19 vaccine dose if the person is age 18 years or older. People who receive Janssen COVID-19 Vaccine after a dose of an mRNA COVID-19 vaccine should be considered to have received a valid, single-dose Janssen primary series.

Any age-appropriate mRNA vaccine can be used for the booster dose(s): it can be the same mRNA vaccine as the primary series (homologous booster) or a different mRNA vaccine (heterologous booster). The Janssen COVID-19 Vaccine cannot be used as a second booster dose.

Coadministration of COVID-19 vaccines with other vaccines

COVID-19 vaccines may be administered without regard to timing of other vaccines. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day.

Extensive experience with non-COVID 19 vaccines has demonstrated that immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone. Data assessing the outcomes of simultaneous administration of COVID-19 vaccines with other vaccines are limited currently, including any potential increase in reactogenicity when COVID-19 and other vaccines are administered at the same visit.

In accordance with general best practices, routine administration of all age-appropriate doses of vaccines simultaneously is recommended for children for whom no specific contraindications exist at the time of the healthcare visit. When deciding whether to coadminister another vaccine(s) with COVID-19 vaccine, providers and parents/guardians may consider whether a child is behind or at risk of becoming behind on recommended vaccines and the likelihood of the child returning for another vaccination; the child's risk of becoming infected with a vaccine-preventable disease and their risk for severe disease if infected; and the reactogenicity profile of the vaccines.

Best practices for multiple injections include:

- Label each syringe with the name and the dosage (amount) of the vaccine, lot number, initials of the preparer, and exact beyond-use time, if applicable.
- Administer each injection in a different injection site; separate injection sites by 1 inch or more, if possible.
- Administer the COVID-19 vaccine and vaccines that may be more likely to cause a local reaction in different limbs, if possible.

See ACIP's general best practices and *Epidemiology and Prevention of Vaccine-Preventable Diseases* (Pink Book) for further information.

Transitioning from a younger to older age group

People should receive the recommended age-appropriate vaccine dosage based on their age on the day of vaccination. If a person moves from a younger age group to an older age group during the primary series or between the primary series and receipt of the booster dose(s), they should receive the vaccine product and dosage for the older age group for all subsequent doses.

FDA authorization allows for different dosing for certain age transitions as described below. Refer to Table 1 for information about age-specific vaccine products and dosages.

about age-specific vaccine products and dosages.

Pfizer-BioNTech COVID-19 Vaccine

Children who will turn from age 4 years to 5 years: FDA authorization of the Pfizer-BioNTech COVID-19 Vaccine allows children who will turn from age 4 years to 5 years between any dose in the primary series to receive:

- A 2-dose primary series using the Pfizer-BioNTech COVID-19 Vaccine product authorized for children ages 5–11 years

or

- A 3-dose primary series initiated with the Pfizer-BioNTech COVID-19 Vaccine product authorized for children ages 6 months–4 years. Each of doses 2 and 3 may be with the Pfizer-BioNTech COVID-19 Vaccine product authorized for children ages 6 months–4 years, **or** the Pfizer-BioNTech COVID-19 Vaccine product authorized for children ages 5–11 years.

Children who will turn from age 11 years to 12 years: FDA authorization of the Pfizer-BioNTech COVID-19 Vaccine allows children who will turn from age 11 years to 12 years between their first and second dose in the primary series to receive, for either dose: (1) the Pfizer-BioNTech COVID-19 Vaccine product authorized for children ages 5–11 years or (2) the Pfizer-BioNTech COVID-19 Vaccine product authorized for people ages 12 years and older.

Vaccination after SARS-CoV-2 Infection

For information on the timing of COVID-19 vaccination (primary and booster dose[s]) after SARS-CoV-2 infection, see COVID-19 vaccination and SARS-CoV-2 infection.

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Patient counseling

Pre-vaccination counseling

The vaccine-specific EUA or EUI Fact Sheet for Recipients and Caregivers should be provided to all vaccine recipients, parents or guardians, and caregivers (when relevant) before vaccination with any currently FDA-approved or FDA-authorized COVID-19 vaccine. Both Fact Sheets do not need to be given; whether the EUA or EUI Fact Sheet should be given is determined by which COVID-19 vaccine and dose is administered.

Vaccine recipients should be informed that mRNA vaccines are preferred and that the Janssen COVID-19 Vaccine should only be used in limited situations due to the risk of TTS following receipt of the Janssen COVID-19 Vaccine. Those who elect to receive the Janssen COVID-19 Vaccine should be informed about the risk and symptoms of TTS that can occur (typically in the 2 weeks after vaccination), as well as the need to seek immediate medical care should symptoms develop. See Safety considerations for Janssen COVID-19 Vaccine.

People receiving mRNA COVID-19 vaccines, especially males ages 12–39 years, should be made aware of the rare risk of myocarditis and/or pericarditis following receipt of mRNA COVID-19 vaccines. Counseling should include the need to seek care if symptoms of myocarditis or pericarditis develop after vaccination, particularly in the week after vaccination. See Safety Considerations for mRNA vaccines.

For more information on patient counseling, see Vaccine Recipient Education.

Potential for local and systemic reactions

Before vaccination, providers should counsel COVID-19 vaccine recipients, parents, or guardians about common local (e.g., pain, swelling, erythema at the injection site) and systemic (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) post-vaccination reactions. Localized axillary lymphadenopathy on the same side as the vaccinated arm or groin, if vaccination was in the thigh, has been observed following vaccination with mRNA COVID-19 vaccines *(4)*. Among younger children, particularly those younger than ages 3 years, systemic reactions also can include irritability/crying, sleepiness, and loss of appetite.

Anaphylactic reactions have been rarely reported following receipt of COVID-19 vaccines. Administration of antihistamines before COVID-19 vaccination to prevent allergic reactions is not generally recommended. However, while antihistamines will not prevent anaphylaxis, some experts advise antihistamine use as a means of preventing milder allergic reactions in patients who might be at higher risk for allergic reactions.

Management of post-COVID-19-vaccination symptoms

For all currently FDA-approved or FDA-authorized COVID-19 vaccines, antipyretic or analgesic medications can be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate; these medications should not be used prophylactically for the purposes of prevention of post-vaccination symptoms. However, in general, aspirin is not recommended for use in children and adolescents ages 17 years and younger as an antipyretic or analgesic due to the risk of Reye's syndrome.

Additional guidance is available for assessing and responding to post-vaccination signs and symptoms in workplaces, including healthcare settings, and among long-term care facility residents.

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Laboratory testing

Vaccination and SARS-CoV-2 testing

Antibody testing is not currently recommended to assess the need for vaccination in an unvaccinated person or to assess immunity to SARS-CoV-2 following COVID-19 vaccination. If antibody testing was done, vaccination with the primary series, an additional dose, or a booster dose should be completed as recommended regardless of the antibody test result. SARS-CoV-2 antibody tests currently authorized under an EUA have variable performance characteristics and limitations. Furthermore, serologic correlates of protection have not been established and antibody testing does not evaluate the cellular immune response.

Screening testing and vaccination

Unvaccinated people who are being screened for SARS-CoV-2 infection (e.g., work, school, travel requirement) may be vaccinated at the time of screening if they do not have symptoms consistent with COVID-19.

Interpretation of SARS-CoV-2 test results in vaccinated people

Prior receipt of a COVID-19 vaccine will not affect the results of SARS-CoV-2 viral tests (nucleic acid amplification or antigen tests). To evaluate for antibody evidence of prior infection in vaccinated people (e.g., for public health surveillance), a test that specifically detects IgM/IgG to the nucleocapsid protein should be used.

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Contraindications and precautions

CDC considers COVID-19 vaccination to be contraindicated, not recommended, or a precaution in the following situations:

Table 4. Contraindications and precautions to COVID-19 vaccination

Medical condition or history	Guidance	Recommended action(s)
History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine	Contraindication	Do not vaccinate with the same type of COVID-19 vaccine (i.e., mRNA or Janssen COVID-19 Vaccine). See Appendix E for actions and

Medical condition or history	Guidance	Recommended action(s)
History of a known diagnosed allergy to a component of the COVID-19 vaccine	Contraindication	additional information.
For **the Janssen COVID-19 Vaccine**, TTS following receipt of a previous Janssen COVID-19 Vaccine (or other COVID-19 vaccines not currently authorized in the United States that are based on adenovirus vectors, e.g., AstraZeneca)	Contraindication	Do not vaccinate with Janssen COVID-19 Vaccine. See Safety considerations for Janssen COVID-19 Vaccine for additional information on vaccinating this group with an mRNA COVID-19 vaccine.
For **the Janssen COVID-19 Vaccine**, history of an episode of immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as spontaneous or classic HIT	Not recommended	Do not vaccinate with Janssen COVID-19 Vaccine. These people should receive an mRNA COVID-19 vaccine.
For the **Janssen COVID-19 Vaccine**, GBS within 6 weeks after receipt of Janssen COVID-19 Vaccine	Not recommended	Do not vaccinate with Janssen COVID-19 Vaccine. These people should receive an mRNA COVID-19 vaccine.
History of an immediate allergic reaction to any vaccine other than COVID-19 vaccine or to any injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"])	Precaution	The benefit of vaccination outweighs the risks for most people. See Appendix E for actions and additional information.
People with a history of a non-severe, immediate (onset less than 4 hours) allergic reaction after a dose of one type of COVID-19 vaccine (i.e., mRNA or Janssen) have a precaution to the **same type of COVID-19 vaccine**	Precaution	
People with an allergy-related contraindication to one type of COVID-19 vaccine have a precaution to the **other type of COVID-19 vaccine** (e.g., people with a contraindication to an mRNA COVID-19 vaccine have a precaution to Janssen COVID-19 vaccine and vice versa).	Precaution	
Moderate or severe acute illness, with or without fever	Precaution	Defer vaccination until the illness has improved.
History of MIS-C or MIS-A	Precaution	See COVID-19 vaccination and MIS-C and MIS-A
For **mRNA COVID-19 vaccines**, history of myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine	Precaution	A subsequent dose of any COVID-19 vaccine should generally be avoided. See Safety considerations for mRNA COVID-19 vaccines: Pfizer-BioNTech and Moderna for additional considerations.
For **Janssen COVID-19 Vaccine**, a history of GBS	Precaution	See Safety considerations for Janssen COVID-19 Vaccine and Special situations and populations for additional information.

Abbreviations: TTS = thrombosis with thrombocytopenia syndrome; HIT = heparin-induced thrombocytopenia; GBS = Guillain-Barré syndrome; MIS-C = multisystem inflammatory syndrome in children; MIS-A = multisystem inflammatory syndrome in adults

An **immediate allergic reaction** to a vaccine or injectable therapy is defined as any hypersensitivity-related signs or symptoms such as urticaria (hives), angioedema (visible swelling), respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occurs within four hours following administration.

Severe allergic reactions include:

- Possible anaphylaxis, a progressive life-threatening reaction that typically includes urticaria but also with other symptoms such as wheezing, difficulty breathing, or low blood pressure (see Appendix E)
- Any angioedema affecting the airway (i.e., tongue, uvula, or larynx)
- Diffuse rash which also involves mucosal surfaces (e.g., Stevens-Johnson Syndrome)

Non-severe allergic reactions include:

- Urticaria beyond the injection site
- Angioedema involving lips, facial skin, or skin in other locations. NOTE: Any angioedema affecting the airway (i.e., tongue, uvula, or larynx) is considered a severe allergic reaction (see above)

See:

- Appendix E for triage of people with a history of allergies or allergic reactions
- FDA EUA fact sheets and U.S. COVID-19 Vaccine Product Information for full list of vaccine ingredients
- Managing Anaphylaxis for information on allergic reactions, including severity of allergic reactions

Risk assessment: The following considerations can be used to help the vaccination provider conduct a risk assessment for vaccination in people with a precaution to vaccination because of allergy:

- Risk of exposure to SARS-CoV-2 virus (e.g., because of occupational or institutional setting)
- Risk of severe disease or death due to COVID-19 (e.g., because of age, underlying medical conditions)
- The unknown risk of anaphylaxis following COVID-19 vaccination in a person with a history of an immediate allergic reaction to other vaccines or injectable therapies. Consultation with an allergist-immunologist may help to clarify the risk assessment for these people.
- Ability of the patient to be vaccinated in a setting where appropriate medical care is immediately available for anaphylaxis. For people with a contraindication due to allergy to one type of COVID-19 vaccines (e.g., mRNA vaccines), who are receiving another type (e.g., Janssen vaccine) and for people with an immediate, non-severe allergic reaction after a previous dose of COVID-19 vaccine who are receiving vaccination with a subsequent dose of that COVID-19 vaccine type, vaccination should only be undertaken in an appropriate setting under the supervision of a healthcare professional experienced in the management of severe allergic reactions. Consultation with an allergist-immunologist may help to clarify the risk assessment for these people.

Healthcare professionals and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project for a complex COVID-19 vaccine safety question not readily addressed by CDC guidance.

Observation periods following vaccination to monitor for allergic reactions

CDC recommends the following observation periods after COVID-19 vaccination:

- 30 minutes:
  - People with a contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to mRNA COVID-19 vaccines who receive Janssen vaccine).
  - History of non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine.
  - History of an immediate allergic reaction of any severity to non-COVID-19 vaccines or injectable therapies.
  - History of anaphylaxis due to any cause.
- 15 minutes: All other people

Management of anaphylaxis after COVID-19 vaccination

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of COVID-19 vaccine. Further information on anaphylaxis management can be found in the interim considerations for the management of anaphylaxis following COVID-19 vaccination and laboratory evaluation of people who experience anaphylaxis after vaccination.

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Reporting of vaccine adverse events

Adverse events that occur in a recipient following COVID-19 vaccination should be reported to VAERS. Vaccination providers are required by FDA to report the following that occur after COVID-19 vaccination under BLA or EUA:

- Vaccine administration errors
- Serious adverse events
- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death

- Cases of COVID-19 that result in hospitalization or death

Reporting is encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967.

In addition, CDC has developed a new voluntary, smartphone-based tool, **v-safe.** This tool uses text messaging and web surveys to provide near real-time health check-ins after patients receive COVID-19 vaccination. Reports to **v-safe** indicating a medically significant health impact, including pregnancy, are followed up by the CDC/**v-safe** call center to collect additional information to complete a VAERS report, if appropriate.

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Safety considerations for mRNA COVID-19 vaccines: Pfizer-BioNTech and Moderna

Post-vaccination symptoms

In clinical trials of Pfizer-BioNTech and Moderna COVID-19 vaccines, types of post-vaccination reactions were generally similar. Pain at the injection site, sometimes severe, was the most frequent local reaction. Fatigue, headache, and myalgia were the most common systemic symptoms. Most systemic symptoms were mild to moderate in severity, occurred within 1-2 days of vaccination, and resolved within 1-2 days of onset. Overall, symptoms tended to be more frequent and severe following the second dose of vaccine and among adolescents and younger adults compared with older adults.

Among children ages 6 months–4 years (Pfizer-BioNTech) or 6 months–5 years (Moderna), pain/tenderness at the injection site was the most frequent local reaction. The most common systemic symptom in older children was fatigue; in younger children (ages 6–23 months), irritability/crying and drowsiness/sleepiness were most common. Most systemic symptoms were mild to moderate in severity, typically began 1–2 days after vaccination, and resolved after 1–2 days.

Febrile seizures can occur in infants and young children ages 6 months–5 years with any condition that causes a fever (most common with high fevers), including COVID-19 . Febrile seizures are uncommon after vaccination. Febrile seizures were rare in COVID-19 vaccine clinical trials for young children. In most cases, simultaneous vaccination does not lead to higher rates of febrile seizures, although administering more than one vaccine at the same clinic visit has been associated with increased risk for febrile seizures in some studies of young children. The impact of coadministration of COVID-19 and routine vaccines on the risk of febrile seizures has not been specifically studied. CDC will monitor for febrile seizures following COVID-19 vaccination in young children.

Syncope (fainting) may occur in association with any injectable vaccine, especially in adolescents. Procedures should be in place to prevent falling injuries and manage syncopal reactions. People should be seated or lying down during vaccination. Vaccine providers, particularly when vaccinating adolescents, should consider observing vaccine recipients for 15 minutes after vaccination to decrease the risk for injury should they faint. If syncope develops, patients should be observed until symptoms resolve.

Unless people have a contraindication to vaccination, they should be encouraged to complete the series to optimize protection against COVID-19 even if they experience local or systemic symptoms following the first dose.

Myocarditis and pericarditis

A rare risk for myocarditis and/or pericarditis has been observed following receipt of mRNA COVID-19 vaccines. These rare cases of myocarditis or pericarditis have occurred most frequently in adolescent and young adult males within the first week after receiving the second dose of an mRNA COVID-19 vaccine. The reporting rates for myocarditis after mRNA COVID-19 vaccination exceed the background rates in several age groups in males and females. Some, but not all,

observational analyses of postmarketing data suggest that there may be an increased risk of myocarditis and pericarditis in males ages 18–39 years following the second dose of Moderna COVID-19 Vaccine relative to other authorized or approved mRNA COVID-19 vaccines.

To date, data suggest the risk for myocarditis and/or pericarditis after mRNA COVID-19 booster doses in adolescents and young adults is generally lower than the risk after the second mRNA COVID-19 vaccination.

No cases of myocarditis or pericarditis were reported in children in the pre-authorization clinical trials of Pfizer-BioNTech (ages 6 months–4 years) or Moderna (ages 6 months–5 years) vaccines. In postmarketing surveillance, cases of myocarditis and pericarditis among children ages 5–11 years after Pfizer-BioNTech COVID-19 vaccination have been rarely reported, primarily in males and after dose 2. However, it is not yet known if this represents an increased risk of myocarditis. Safety monitoring is ongoing to assess for possible risk of myocarditis and pericarditis after mRNA COVID-19 vaccination in all age groups.

Most patients with myocarditis after mRNA COVID-19 vaccination have been hospitalized for short periods. CDC is assessing long-term outcomes in people with myocarditis after mRNA COVID-19 vaccination. Preliminary data from surveys conducted with healthcare providers caring for persons ages 5-29 years at least 90 days after the myocarditis diagnosis showed most patients were fully recovered from their myocarditis.

After reviewing available data on the risks and benefits, ACIP and CDC determined that the benefits (e.g., prevention of COVID-19 cases and its severe outcomes) outweigh the risks of myocarditis and pericarditis after receipt of mRNA COVID-19 vaccines for children , adolescents, and young adults.

People receiving mRNA COVID-19 vaccines, especially males ages 12–39 years, should be made aware of the rare risk of myocarditis and/or pericarditis following receipt of mRNA COVID-19 vaccines and the benefit of COVID-19 vaccination in reducing the risk of severe outcomes from COVID-19, including the possibility of cardiac sequelae. Counseling should include the need to seek care if symptoms of myocarditis or pericarditis, such as chest pain, shortness of breath, or tachycardia develop after vaccination, particularly in the week after vaccination. In younger children, symptoms of myocarditis may also include non-specific symptoms such as irritability, vomiting, poor feeding, tachypnea, or lethargy. Extending the interval between the first and second mRNA vaccine dose to 8 weeks might reduce the risk.

Myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine but before administration of a subsequent dose of COVID-19 vaccine

Development of myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine is a precaution to a subsequent dose of any COVID-19 vaccine and subsequent doses should generally be avoided.

Until additional safety data are available, experts advise that people who develop myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine generally **should not** receive a subsequent dose of any COVID-19 vaccine. If, after a risk assessment, the decision is made to administer a subsequent COVID-19 vaccine dose, the person should wait until at least after their episode of myocarditis or pericarditis has resolved (i.e., resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by patient's clinical team). For men ages 18 years and older who choose to receive a subsequent COVID-19 vaccine, some experts advise the use of Janssen COVID-19 Vaccine be considered instead of mRNA COVID-19 vaccines. These people should be aware of the risk of TTS. Considerations for subsequent vaccination may include:

- The myocarditis or pericarditis was considered unrelated to mRNA COVID-19 vaccination (e.g., due to SARS-CoV-2 or other viruses), especially if the myocarditis or pericarditis diagnosis occurred more than 3 weeks after the most recent dose of COVID-19 vaccine
- Personal risk of severe acute COVID-19 (e.g., age, underlying conditions)
- COVID-19 community level and personal risk of infection
- Timing of any immunomodulatory therapies; ACIP's general best practice guidelines for immunization can be consulted for more information

History of myocarditis or pericarditis prior to COVID-19 vaccination

People who have a history of myocarditis or pericarditis unrelated to mRNA COVID-19 vaccination (e.g., due to SARS-CoV-2 or other viruses) may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved. This includes resolution of symptoms attributed to myocarditis or pericarditis, as well

or pericarditis has completely resolved. This includes resolution of symptoms attributed to myocarditis or pericarditis, as well as no evidence of ongoing heart inflammation or sequelae as determined by the person's clinical team.

History of other heart disease

People who have a history of other heart disease, including congenital heart disease and Kawasaki disease, may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine.

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Safety considerations for Janssen COVID-19 Vaccine

Post-vaccination symptoms

In clinical trials of the Janssen COVID-19 Vaccine, pain at the injection site was the most frequently reported local reaction among vaccine recipients; erythema and swelling were reported less frequently. Fatigue and headache were the most commonly reported systemic reactions. Most systemic symptoms were mild to moderate in severity and resolved within 1–2 days. Overall, symptoms were more frequent in people ages 18–59 years compared to people ages 60 years and older.

Thrombosis with thrombocytopenia syndrome (TTS)

TTS is a rare syndrome that includes acute venous or arterial thrombosis and new onset thrombocytopenia in patients with no recent known exposure to heparin. Although the condition is rare, currently available evidence supports a causal relationship between Janssen COVID-19 Vaccine and TTS. Cases of TTS, including deaths, following administration of the Janssen COVID-19 Vaccine have been reported in males and females, with the highest risk in females ages 30-49 years.

Based on an updated risk-benefit analysis , COVID-19 vaccine recipients should be informed that mRNA COVID-19 vaccines are preferred over the Janssen COVID-19 Vaccine. Due to the risk of TTS, the Janssen COVID-19 Vaccine should only be used in limited situations :

- When there is a contraindication to mRNA COVID-19 vaccines (e.g., severe allergic reaction after a previous dose or to a component of an mRNA COVID-19 vaccine)
- When a person would otherwise remain unvaccinated for COVID-19 due to limited access to mRNA COVID-19 vaccines
- When a person wants to receive the Janssen COVID-19 Vaccine despite the safety concerns identified

All people who elect to receive Janssen COVID-19 Vaccine should be informed about the risk and symptoms of TTS that could occur after vaccination (typically within 2 weeks after receipt), the need to seek immediate medical care should such symptoms develop at any time, and the availability of mRNA COVID-19 vaccines instead of the Janssen COVID-19 Vaccine. This guidance applies to the both primary and booster doses of Janssen COVID-19 Vaccine. People should seek medical attention immediately if they develop any of the following symptoms:

- Shortness of breath
- Chest pain
- Leg swelling
- Persistent abdominal pain
- Severe or persistent headaches or blurred vision
- Easy bruising or tiny blood spots under the skin beyond the site of the injection

It is contraindicated to administer Janssen COVID-19 Vaccine to people with a history of TTS following receipt of the Janssen COVID-19 Vaccine or any other adenovirus vector-based COVID-19 vaccines (e.g., AstraZeneca's COVID-19 Vaccine, which is not FDA-authorized or FDA-approved in the United States). These people should receive a dose of an mRNA COVID-19 vaccine as a booster at least 2 months following their dose of the Janssen COVID-19 Vaccine and after their clinical condition has stabilized. Prior to booster vaccination, a conversation between the patient and their clinical team, including a hematologist or

other specialists, may assist with decisions about using an mRNA COVID-19 vaccine as a booster and the timing of the booster vaccination. For information on the second booster dose, see guidance for people who are **not** moderately or severely immunocompromised and guidance for people who are moderately or severely immunocompromised.

Clinicians should consult guidance from the American Society of Hematology for information on the diagnosis and treatment of suspected cases of TTS, and report any occurrence of TTS to VAERS .

People with a history of thrombosis or risk factors for thrombosis

Although the mechanism of TTS associated with the Janssen COVID-19 Vaccine is unclear, it appears to be similar to another rare immune-mediated syndrome, spontaneous heparin-induced thrombocytopenia (HIT).

People with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as spontaneous or classic HIT, should not receive Janssen COVID-19 Vaccine. These people should receive a currently FDA-approved or FDA-authorized mRNA COVID-19 vaccine.

Available evidence does not indicate that other thromboembolic conditions (e.g., inherited or acquired thrombophilia, pregnancy, hormonal contraception use) increase the risk of TTS.

Guillain–Barré syndrome (GBS)

Vaccine safety monitoring suggests an elevated risk of GBS after Janssen COVID-19 vaccination with proportionally more GBS cases observed after Janssen COVID-19 vaccination compared with mRNA COVID-19 vaccination. The highest risk has been observed in people ages 40-64 years, with symptoms of GBS beginning within 42 days after Janssen COVID-19 vaccination; most GBS reports have been in males.

People should seek medical attention immediately if they develop any of the following symptoms after receiving Janssen COVID-19 Vaccine:

- Weakness or tingling sensations, especially in the legs or arms, that is worsening and spreading to other parts of the body
- Difficulty walking
- Difficulty with facial movements, including speaking, chewing, or swallowing
- Double vision or inability to move eyes
- Difficulty with bladder control or bowel function

Development of GBS after receipt of Janssen COVID-19 Vaccine is a precaution for receiving subsequent dose(s) of the Janssen COVID-19 Vaccine. People who develop GBS within 6 weeks after receipt of Janssen COVID-19 Vaccine should not receive another dose of Janssen COVID-19 Vaccine. An mRNA COVID-19 vaccine should be used for any subsequent doses. Providers should also strongly consider using an mRNA COVID-19 vaccine for subsequent doses in people who had GBS onset beyond 6 weeks after receipt of Janssen COVID-19 Vaccine. Any occurrence of GBS following COVID-19 vaccination should be reported to VAERS.

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COVID-19 vaccination and SARS-CoV-2 infection

People with a known or potential COVID-19 exposure

COVID-19 vaccines are not recommended for post-exposure prophylaxis to prevent SARS-CoV-2 infection. Unvaccinated people who were close contacts of a person with SARS-CoV-2 infection should typically not seek vaccination until quarantine has ended; this is to reduce the risk of transmission to others (e.g., healthcare personnel, other clinic patients). Vaccination is

not expected to prevent SARS-CoV-2 infection that could occur after the exposure, and it will avoid confusion between vaccination side effects and symptoms of COVID-19.

In certain circumstances, to avoid missed opportunities for vaccination, vaccination during quarantine could be considered during outreach and contact tracing activities or at the time of post-exposure SARS-CoV-2 testing. Examples might include when people 1) are likely to have repeated SARS-CoV-2 exposures because they are unable to effectively quarantine (e.g., residing in a congregate or crowded setting or during outbreaks in their community), or, 2) will have limited access to vaccination after their quarantine period has ended, or, 3) are unlikely to otherwise seek vaccination after their quarantine period has ended. In such situations, the person recommended for quarantine can receive vaccination as long as 1) they do not have symptoms consistent with COVID-19 or current SARS-CoV-2 infection, and, 2) appropriate infection prevention and control procedures are employed during vaccination.

However, they should also be informed that vaccination may not prevent SARS-CoV-2 infection until 2 weeks after the primary series is completed, i.e., will not prevent them from getting COVID-19 from the current exposure but should help protect them from infection after future exposures. In addition, SARS-CoV-2 viral testing may be necessary to differentiate between common post-vaccination symptoms and symptoms of SARS-CoV-2 infection:

- People who develop signs and symptoms associated with COVID-19 (e.g., cough, shortness of breath, runny nose, sore throat, loss of taste or smell) should isolate and be evaluated for SARS-CoV-2 infection as soon as possible.
- People who develop signs and symptoms that could be from either COVID-19 vaccination or SARS-CoV-2 infection (e.g., fever, fatigue, headache, myalgia) without typical COVID-19 symptoms described above, and are clinically stable, should isolate and, if symptoms do not improve by two days post-vaccination, be evaluated for SARS-CoV-2 infection.

People with prior or current SARS-CoV-2 infection

COVID-19 vaccination is recommended for everyone ages 6 months and older, regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection. This includes people with prolonged post-COVID-19 symptoms and applies to primary series and booster doses. This recommendation also applies to people who experience SARS-CoV-2 infection after receiving any COVID-19 dose.

Growing epidemiologic evidence indicates that vaccination following SARS-CoV-2 infection further increases protection from subsequent infection and hospitalization, including in the setting of increased circulation of more infectious SARS-CoV-2 strains.

People with known current SARS-CoV-2 infection should defer any COVID-19 vaccination, including booster vaccination, at least until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.

In addition, people who recently had SARS-CoV-2 infection may consider delaying a primary series dose or their first or second COVID-19 vaccine booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic). Studies have shown that increased time between infection and vaccination may result in an improved immune response to vaccination. Also, a low risk of reinfection has been observed in the weeks to months following infection. Individual factors such as risk of COVID-19 severe disease, COVID-19 community level, or characteristics of the predominant SARS-CoV-2 strain should be taken into account when determining whether to delay getting a COVID-19 vaccination after infection.

Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection is not recommended for the purpose of vaccine decision-making.

People who received SARS-CoV-2 antibody-based products

People who previously received antibody products (anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment, post-exposure prophylaxis, or pre-exposure prophylaxis can be vaccinated at any time; COVID-19 vaccination does not need to be delayed following receipt of monoclonal antibodies or convalescent plasma. Although some reduction in vaccine-induced antibody titers was observed in people who previously received antibody products, the

clinical significance of this reduction is unknown, and the balance of benefits vs. risks favors proceeding with vaccination even considering the possibility of diminished vaccine effectiveness in this situation. Those who received antibody products due to a recent SARS-CoV-2 infection should follow the guidance in the section above.

However, in people who previously received a COVID-19 vaccine, administration of tixagevimab/cilgavimab (EVUSHELD™) for pre-exposure prophylaxis should be deferred for at least two weeks after vaccination, per the product EUA .

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COVID-19 vaccination and MIS-C and MIS-A

MIS-C is a rare but severe condition in children and adolescents infected with SARS-CoV-2. MIS-A, a similar condition in adults, is even rarer and less well characterized. Both include a dysregulated immune response to SARS-CoV-2 infection. There are limited data on the safety of COVID-19 vaccines in people who have had MIS-C or MIS-A. The risk of recurrence of a dysregulated immune response following reinfection with SARS-CoV-2 or an MIS-like illness following COVID-19 vaccination is unknown.

Considerations for initiating COVID-19 vaccination in people with a history of MIS-C or MIS-A

Children and adolescents with a history of MIS-C

Experts consider the benefits of COVID-19 vaccination for children and adolescents with a history of MIS-C (i.e., a reduced risk of severe disease including potential recurrence of MIS-C after reinfection) to outweigh a theoretical risk of an MIS-like illness or the risk of myocarditis following COVID-19 vaccination for those who meet the following three criteria:

1. Clinical recovery has been achieved, including return to normal cardiac function;
2. It has been at least 90 days after the diagnosis of MIS-C; and
3. The patient resides in an area where the COVID-19 community level is high or is otherwise at increased risk for exposure to SARS-CoV-2 (e.g., through occupation, travel, large gatherings)

COVID-19 vaccination may also be considered for children and adolescents who had MIS-C and **do not meet all three criteria**, at the discretion of their clinical care team (see Consultation for decisions about COVID-19 vaccination). Experts view clinical recovery, including return to normal cardiac function, as an important factor when considering COVID-19 vaccination. Additional factors, such as the risk of severe COVID-19 due to certain medical conditions, may also be considered.

Adults with a history of MIS-A

COVID-19 vaccination may be considered for adults who had MIS-A at the discretion of their clinical care team (see Consultation for decisions about COVID-19 vaccination). Experts view clinical recovery, including return to normal cardiac function, as an important factor when considering COVID-19 vaccination. Additional factors, such as risk of severe COVID-19 due to age or certain medical conditions, may also be considered.

Timing of COVID-19 vaccination

Initiation of COVID-19 vaccination in people with a history of MIS-C or MIS-A should take into consideration current or planned immunomodulatory therapies for treatment of MIS-C or MIS-A (see Considerations for timing of COVID-19 vaccination in relation to immunosuppressive therapies).

Considerations for people diagnosed with MIS-C or MIS-A after COVID-19 vaccination

Evaluation of people who develop MIS-C or MIS-A after COVID-19 vaccination

In the rare instance a person develops MIS-C, MIS-A, or a similar clinical illness after receipt of COVID-19 vaccine, referral to a specialist in infectious diseases, rheumatology, and/or cardiology should be considered.

Assessment should include testing for current or prior SARS-CoV-2 infection. Obtaining a serum sample before any intravenous immune globulin (IVIG) is administered is highly recommended so that the sample can be tested for SARS-CoV-2 anti-nucleocapsid antibody, which may require a reference laboratory. Treatment should not be delayed until test results are available. A positive anti-nucleocapsid antibody test result indicates prior SARS-CoV-2 infection. (To test for current SARS-CoV-2 infection, a molecular diagnostic or antigen test should be used). Anti-spike protein antibody testing cannot be used to determine SARS-CoV-2 infection status in a vaccinated person because a positive test result can be induced by either COVID-19 vaccination or SARS-CoV-2 infection.

Decisions about administration of subsequent COVID-19 vaccine doses in people who develop MIS-C or MIS-A after COVID-19 vaccination depend on timing of MIS in relation to vaccination, clinical recovery, and epidemiologic considerations.

Administration of subsequent COVID-19 vaccine doses: Onset of MIS 90 days or more after most recent COVID-19 dose

Children with MIS-C: Administration of subsequent COVID-19 vaccine dose(s) should be considered for those who meet the three criteria listed above:

1. Clinical recovery has been achieved, including return to normal cardiac function;
2. It has been at least 90 days after the diagnosis of MIS-C; and
3. The patient resides in an area where the COVID-19 community level is high or is otherwise at increased risk for exposure to SARS-CoV-2 (e.g., through occupation, travel, large gatherings)

For children and adolescents who had MIS-C but do not meet all three criteria above, see Consultation for decisions about COVID-19 vaccination.

Adults with MIS-A: See Consultation for decisions about COVID-19 vaccination.

Administration of subsequent COVID-19 vaccine doses: Onset of MIS fewer than 90 days after most recent COVID-19 dose

Children with MIS-C: Subsequent COVID-19 vaccine dose(s) should be deferred at this time until additional data are available. However, on a case-by-case basis, a provider may offer subsequent dose(s) if the three criteria above are met and there is strong evidence that the MIS-C was a complication of a recent SARS-CoV-2 infection.

Adults with MIS-A: See Consultation for decisions about COVID-19 vaccination.

Consultation for decisions about COVID-19 vaccination

A conversation between the patient and/or their guardian(s) and their clinical team or a specialist (e.g., infectious diseases, rheumatology, and/or cardiology) is strongly encouraged to assist with decisions about the use of COVID-19 vaccines in the setting of MIS-C or MIS-A.

For complicated situations, not addressed by the guidance above, healthcare and public health professionals may consider requesting a consultation from the Clinical Immunization Safety Assessment COVIDvax project. An illness consistent with MIS-C or MIS-A after receiving COVID-19 vaccine should be reported to VAERS .

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Considerations involving pregnancy, lactation, and fertility

COVID-19 vaccination is recommended for people who are pregnant, lactating, trying to get pregnant now, or who might become pregnant in the future.

Pregnancy

Staying up to date with COVID-19 vaccinations is recommended for people who are pregnant. Although the overall risks are low, pregnant and recently pregnant people (for at least 42 days following the end of pregnancy) with COVID-19 are at increased risk for severe illness and death when compared with non-pregnant people. Additionally, pregnancies affected by COVID-19 are at increased risk for preterm birth and stillbirths, and might be at increased risk for other complications.

A growing body of evidence on the safety and effectiveness of COVID-19 vaccination indicates that the benefits of vaccination outweigh any known or potential risks of COVID-19 vaccination during pregnancy. Recent studies have also shown that antibodies produced after COVID-19 vaccination during pregnancy are transferred to the newborn, and COVID-19 vaccination of people who are pregnant reduces the risk of COVID-19 hospitalization in infants younger than 6 months.

A conversation between the patient and their clinical team may assist with decisions about the use of a COVID-19 vaccine; however, approval by a healthcare professional is not required before vaccination. Data on uptake of COVID-19 vaccination among pregnant people can be found on CDC's COVID Data Tracker.

Side effects can occur after COVID-19 vaccination in pregnant people, similar to those among non-pregnant people. Acetaminophen can be offered as an option for pregnant people experiencing fever (fever has been associated with adverse pregnancy outcomes) or other post-vaccination symptoms.

Lactation

COVID-19 vaccination is recommended for all lactating people. Because clinical trials of COVID-19 vaccines did not include people who were lactating, there are limited data on the safety of COVID-19 vaccines in lactating people or the effects of COVID-19 vaccines on the breastfed infant, milk production, and milk secretion. Recent reports have shown that the antibodies developed from mRNA COVID-19 vaccination received both during and after pregnancy were present in breastmilk samples. More data are needed to determine if these antibodies convey protection against SARS-CoV-2 infection for neonates and infants.

Fertility

There is currently no evidence that any vaccines, including COVID-19 vaccines, cause fertility problems. There is no recommendation for routine pregnancy testing before receipt of a COVID-19 vaccine. Those who are trying to become pregnant do not need to avoid pregnancy after COVID-19 vaccination.

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Special populations

Infants and young children

In accordance with general best practices, preterm infants (infants born before 37 weeks' gestation), regardless of birth weight, should receive COVID-19 vaccination at their chronological age and according to the same schedule and guidance as for full-term infants and children (see Table 2).

Infants of mothers who were vaccinated and/or had COVID-19 or SARS-CoV-2 infection before or during pregnancy should be vaccinated according to the recommended schedule (see Table 2).

People with autoimmune conditions

People with autoimmune conditions may receive any age-appropriate FDA-approved or FDA-authorized COVID-19 vaccine but, as with the general population, mRNA vaccines are preferred over the Janssen COVID-19 Vaccine. If people with these conditions are immunocompromised because of medications such as high-dose corticosteroids or biologic agents, they

should consult guidance for people who are moderately or severely immunocompromised.

People with a history of Bell's palsy

Rare cases of Bell's palsy (acute peripheral facial nerve palsy) were reported following vaccination of participants in mRNA COVID-19 vaccine clinical trials, but FDA was not able to determine whether these cases were causally related to vaccination. People with a history of Bell's palsy may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine.

People with a history of Guillain–Barré syndrome (GBS)

GBS is a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis. For people with a history of GBS, as with the general population, an mRNA COVID-19 vaccine is preferred over Janssen COVID-19 Vaccine. No increased risk of GBS has been identified with mRNA COVID-19 vaccines.

An elevated risk of GBS after receipt of Janssen COVID-19 Vaccine has been observed. A history of GBS is a precaution for receipt of Janssen COVID-19 Vaccine. For people with a history of GBS after Janssen COVID-19 Vaccine, see Considerations for Janssen COVID-19 Vaccine.

People with a history of dermal filler use

Infrequently, people who have received dermal fillers might experience swelling at or near the site of filler injection (usually face or lips) following administration of a dose of an mRNA COVID-19 vaccine. The swelling is temporary and resolves with medical treatment, including corticosteroid therapy. People should be advised to contact their healthcare professional for evaluation if they experience swelling at or near a dermal filler site following vaccination.

People receiving antiviral therapy

Administration of an antiviral drug at any interval before or after vaccination with any of the currently FDA-approved or FDA-authorized COVID-19 vaccines is unlikely to impair development of a protective antibody response.

People undergoing testing for tuberculosis infection

COVID-19 vaccination should not be delayed because of testing for tuberculosis (TB) infection. Testing for TB infection with one of the immune-based methods, either the tuberculin skin test (TST) or an interferon-gamma release assay (IGRA), can be done before, after, or during the same encounter as COVID-19 vaccination.

People undergoing testing for syphilis

FDA has reported that falsely reactive Rapid Plasma Reagin (RPR; non-treponemal) test results can occur with certain RPR tests for at least five months following COVID-19 vaccination in some people. Treponemal testing for syphilis such as *Treponema pallidum* particle agglutination (TP-PA) and treponemal immunoassays do not appear to be impacted by this issue. Per CDC's 2021 Sexually Transmitted Infections Treatment Guidelines, reactive RPR results should be confirmed with treponemal testing (e.g.,TP-PA). Reactive RPR results should be interpreted in the context of the patient's medical history, risk factors, and clinical presentation.

Footnotes

1. COMIRNATY is the proprietary name for the product licensed under the BLA. The Pfizer-BioNTech COVID-19 Vaccine has been available since December 10, 2020 under an EUA. The two approved formulations of COMIRNATY and the two FDA-authorized formulations of the Pfizer-BioNTech COVID-19 Vaccine for people ages 12 years and older are the same formulations, and vials of the BLA-compliant vaccine may bear the name "Pfizer-BioNTech COVID-19 Vaccine." The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the emergency use authorized formulations of Pfizer-BioNTech COVID-19 Vaccine for people ages 12 years and older (purple cap/label and gray cap/label vials), when prepared according to their respective instructions for use, can be used interchangeably without presenting any safety or effectiveness concerns.
2. SPIKEVAX is the proprietary name for the product licensed under the BLA. The Moderna COVID-19 Vaccine has been available since December 18, 2020 under an EUA. The Moderna COVID-19 Vaccine authorized for use in individuals 12

years of age and older (supplied in multiple-dose vials with red caps and labels with light blue borders) has the same formulation as SPIKEVAX. The FDA-approved SPIKEVAX (COVID-19 Vaccine, mRNA) and the emergency use authorized Moderna COVID-19 Vaccine for people ages 12 years and older (supplied in multiple-dose vials with red caps and labels with light blue borders) have the same formulation and can be used interchangeably to provide primary series doses to individuals 12 years of age and older and booster doses to individuals 18 years of age and older without presenting any safety or effectiveness concerns.

3. For intervals of 3 months or less, 28 days (4 weeks) is a "month." For intervals of 4 months or longer, a month is a "calendar month." For age group ranges (e.g., 6 months–4 years, 5–11 years), a dash (–) should be read as "through" and the upper range includes that year through the last day before the birth date.
4. The Society of Breast Imaging has developed Recommendations for the Management of Axillary Adenopathy in Patients with Recent COVID-19 Vaccination which includes considerations for patients and healthcare professionals in scheduling screening exams in relation to the administration of a COVID-19 vaccine.

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Appendices

Appendix A. People who received COVID-19 vaccine outside the United States

The recommendations for people vaccinated outside of the United States depend on the number and type of vaccine(s) received for the primary series and/or booster dose(s). People who initiated vaccination outside of the United States are considered to be up to date with their COVID-19 vaccines when they have completed the recommended actions described below.

Age-appropriate Pfizer-BioNTech and Moderna COVID-19 Vaccine products can be used in people ages 6 months and older to initiate or complete vaccination.* For additional guidance on primary and booster vaccination, see guidance for people who are not moderately or severely immunocompromised and guidance for people who are moderately or severely immunocompromised.

Table A. People who received COVID-19 vaccine outside the United States

Table A.1. Received a COVID-19 vaccine that is FDA-approved or FDA-authorized

Vaccination history	Recommended actions†
Received all recommended primary dose(s)	• Do not repeat primary series. • Administer booster dose(s) if eligible.
Received a partial mRNA COVID-19 vaccine primary series	• Do not restart primary series. • Complete primary series as close to the recommended time as possible, preferably with the same mRNA vaccine. • Administer booster dose(s) if eligible.
Received a booster dose after completion of primary series	• Administer a second booster dose if eligible.

Table A.2. Received a COVID-19 vaccine listed for emergency use by WHO but not approved or authorized by FDA‡

Vaccination history	Recommended actions†
Received all recommended primary doses for that vaccine	• Do not repeat primary series. • Administer booster dose(s) if eligible.
Received partial primary series for that vaccine	• Complete the primary series with mRNA vaccine dose(s) as close to the recommended time as possible. Space from the last WHO-EUL vaccine by at least 28 days. • Administer booster dose(s) if eligible.

Vaccination history	Recommended actions†
Received a booster dose after completion of primary series	• Do not repeat booster dose. • Administer a second booster dose if eligible.

Table A.3. Received a heterologous primary series or booster dose composed of doses of a COVID-19 vaccine listed for emergency use by WHO, at least one of which is not FDA-approved or FDA-authorized‡

Vaccination history	Recommended actions†
Received a complete primary series	• Do not repeat primary series. • Administer booster dose(s) if eligible.
Received a booster dose after completion of primary series	• Do not repeat the booster dose. • Administer a second booster dose if eligible.

Table A.4. Received all or some of the recommended doses of COVID-19 vaccines that are NOT FDA-authorized, FDA-approved, or among those listed for emergency use by WHO

Vaccination history	Recommended actions†
Received any number and combination of vaccine doses	• Do not count doses received toward vaccination in the US. • Start primary series at least 28 days after the last dose of vaccine. • Administer booster dose(s) if eligible.

*The EUI provides a legal framework for heterologous use of mRNA COVID-19 vaccines (i.e., Pfizer-BioNTech and Moderna) in people who received a COVID-19 vaccine outside the US that is not approved or authorized by FDA.

†People ages 5 years and older who received a COVID-19 vaccine that is FDA-authorized, FDA-approved, or listed for emergency use by WHO should receive 1 booster dose if eligible; those ages 12 years and older are able to receive a second booster dose if eligible. For information on booster doses, see guidance for people who are not moderately or severely immunocompromised and guidance for people who are moderately or severely immunocompromised.

‡COVID-19 vaccines that are listed for emergency use by WHO, but are not approved or authorized by FDA, have not been evaluated for efficacy or safety by CDC or ACIP.

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Appendix B. 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 the recommended primary series doses of a vaccine listed for emergency use by WHO (i.e., not placebo) that is not FDA-approved or FDA-authorized are considered to be up to date with their COVID-19 vaccines when they have completed the recommended actions described below. In addition, U.S. trial participants, along with non-U.S.-based participants in the same trial, who received all the recommended primary series doses of a vaccine that is not listed for emergency use by WHO but for which a U.S. data and safety monitoring board or equivalent has independently confirmed efficacy are considered up to date with their COVID-19 vaccines when they have completed the recommended actions described below; at this time, only the Moderna COVID-19 Vaccine in children ages 6–17 years and the Medicago COVID-19 Vaccine in people ages 18 years and older meet these criteria.

- Moderately or severely immunocompromised clinical trial participants should receive a third primary dose of Pfizer-BioNTech COVID-19 Vaccine (ages 6 months and older) or Moderna COVID-19 Vaccine (ages 18 years and older) 28 days after receiving the second vaccine dose of a primary series as detailed in guidance for people who are moderately or severely immunocompromised, unless they have received or plan to receive a third primary dose through a clinical trial.
- Clinical trial participants (including moderately or severely immunocompromised people who received a 3-dose primary series) should receive 1 booster dose of Pfizer-BioNTech COVID-19 Vaccine (ages 5 years and older) or Moderna COVID-19 Vaccine (ages 18 years and older), unless they have received or plan to receive a booster dose through a clinical trial.

- People ages 12 years and older are able to receive a second booster dose if eligible. For information on the second booster dose, see guidance for people who are **not** moderately or severely immunocompromised and guidance for people who are moderately or severely immunocompromised.

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 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.

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Appendix C. Vaccine administration errors and deviations

A vaccine administration error is any preventable event that may cause or lead to inappropriate use of vaccine or patient harm.

The FDA-issued Fact Sheet for Healthcare Providers Administering Vaccines should be referenced for detailed information on storage and handling, dosing and schedule, dose preparation, and administration of COVID-19 vaccines. The information provided below on managing vaccine administration errors should not be interpreted as a recommendation or promotion of unauthorized use of the vaccines.

For all vaccine administration errors:

- Inform the recipient of the vaccine administration error.
- Consult with the state immunization program and/or immunization information system (IIS) to determine how the dose should be entered into the IIS, both as an administered dose and to account for inventory.
- Report the error to the Vaccine Adverse Event Reporting System (VAERS), unless otherwise indicated in the table. Providers are required to report all COVID-19 vaccine administration errors—even those not associated with an adverse event—to VAERS. To file an electronic report, please see the VAERS website .
- Determine how the error occurred and implement strategies to prevent it from happening again. A discussion on strategies to prevent errors can be found in the "Vaccine Administration" chapter of *Epidemiology and Prevention of Vaccine-Preventable Diseases* (Pink Book). Additional resources can be found on CDC's vaccine administration web page, including a job aid for preventing errors.
- Follow the revaccination guidance in the table below, using an age-appropriate COVID-19 vaccine product. Then continue with the recommended schedule of subsequent dose(s) unless otherwise noted (see footnotes to this Appendix).
  - For doses recommended to be repeated, some experts suggest delaying the repeat dose for 8 weeks after the invalid dose based on the potential for increased reactogenicity and the rare risk of myocarditis from mRNA COVID-19 vaccine, particularly in groups at increased risk for myocarditis (e.g., males ages 12–39 years). Individual risk for COVID-19 and the likelihood for an adverse event following COVID-19 vaccination should be taken into consideration when recommending a longer interval. It is acceptable to administer the repeat dose at an interval earlier than 8 weeks as long as the interval is not sooner than the minimal interval noted in Table C: Interim recommendations for COVID-19 vaccine administration errors and deviations.

The recommendations in the table below apply to **all FDA-approved or FDA-authorized COVID-19 vaccines and all doses** (i.e., primary series and booster doses), unless otherwise stated.

Table C. Interim recommendations for COVID-19 vaccine administration errors and deviations

Type	Administration error/deviation	Interim recommendation
Site/route	• Incorrect site (i.e., site other than the deltoid muscle or vastus lateralis muscle)	• Do not repeat dose.

Type	Administration error/deviation	Interim recommendation
	• Incorrect route (e.g., subcutaneous)	• Do not repeat dose. • Inform the recipient of the potential for local and systemic adverse events.
Age	• Unauthorized age group (recipients younger than 6 months)	• Do not give another dose at this time.*

	• Unauthorized age group (recipients ages 6 months–17 years)	• If Moderna vaccine administered:
		  ◦ As a booster dose, do not repeat the dose with Pfizer-BioNTech vaccine
		• If Janssen vaccine administered
		  ◦ As a primary dose, do not count the dose and begin or continue the age-appropriate mRNA COVID-19 vaccine primary series (Table 1) at least 28 days after the Janssen vaccine
		  ◦ As a booster dose, do not count the dose and repeat the dose with Pfizer-BioNTech vaccine at least 28 days after the Janssen vaccine

Product and dosage	• If the incorrect product/dosage is administered, resulting in a higher-than-authorized dose	• Do not repeat dose.†‡
	• If the incorrect product/dosage is administered, resulting in a lower-than-authorized dose	• Repeat dose immediately (no minimum interval) with the age-appropriate product/dosage. • Some experts suggest delaying the repeat dose for 8 weeks after the invalid dose based on the potential for increased reactogenicity and the rare risk of myocarditis from mRNA COVID-19 vaccine, especially in males ages 12-39 years.§‡
	• Higher-than-authorized dose volume administered of the correct product	• Do not repeat dose.†
	• Lower-than-authorized dose volume administered of the correct product (e.g., leaked out, equipment failure, recipient pulled away)	• Repeat dose immediately (no minimum interval).§ • However, if a half-volume dose of vaccine is administered to a patient recommended for the full volume, another half-volume dose can be administered on the same clinic day, and the 2 doses can count as 1 full dose. • See Appendix D for guidance on addressing situations in which a booster dose is administered prior to completing the primary series.
Storage and handling	• Dose administered after improper storage and handling (i.e., temperature excursion)	• Contact the manufacturer for information on the stability of the vaccine. If the manufacturer does not have data to support the stability of the vaccine, repeat the dose immediately (no minimum interval). §
	• Dose administered past the expiration/beyond-use date	• Contact the manufacturer for information on the stability of the vaccine. If the manufacturer does not have data to support the stability of the vaccine, repeat the dose immediately (no minimum interval). §
Intervals¶	• An mRNA primary series dose administered prior to the recommended interval#	• Repeat dose. Space repeat dose after the dose given in error by at least the recommended interval (see Table 2 and Table 3).§

	• Booster dose administered prior to the minimum interval (i.e., for the first booster dose, prior to 2 months after Janssen primary series or 3 months after mRNA vaccine primary series)	• Repeat dose if this is the first booster dose. Space repeat dose after the dose given in error by at least the minimum interval.§
		  ◦ 2-month minimum booster interval after Janssen vaccine primary series
		  ◦ 3-month minimum booster interval after mRNA vaccine primary series
		• Do not repeat dose if this is the second booster dose.

	• Any COVID-19 vaccine dose administered at any interval after the recommended interval	• Do not repeat dose. There is no maximum interval. • This deviation from CDC guidance does not require VAERS reporting.
	• Tixagevimab/cilgavimab (EVUSHELD™) administered less than 14 days after COVID-19 vaccination	• In general, do not repeat vaccine dose. However, based on clinical judgement, a repeat dose of vaccine may be administered at an interval of at least 28 days after the dose of vaccine. §

Type	Administration error/deviation	Interim recommendation
Mixed series	• Incorrect mRNA COVID-19 vaccine product inadvertently administered as part of a 2- or 3-dose primary series	• Do not repeat dose. • Children ages 6 months–4 years who receive different mRNA products for the first 2 doses of an mRNA COVID-19 vaccine series should follow a 3-dose schedule. A third dose of either mRNA vaccine should be administered 8 weeks after the second dose to complete the 3-dose primary series. • Children ages 5–17 years who receive a mixed mRNA COVID-19 vaccine primary series can follow the Pfizer-BioNTech COVID-19 Vaccine schedule and receive a booster dose.
Diluent (Pfizer-BioNTech COVID-19 Vaccine formulations only [purple cap and orange cap])	• ONLY diluent administered (i.e., sterile 0.9% sodium chloride)	• Administer the authorized dose immediately (no minimum interval).
	• No diluent, resulting in higher than authorized dose	• Do not repeat dose.[†] Inform the recipient of the potential for local and systemic adverse events.
	• Incorrect diluent type (e.g., sterile water, bacteriostatic 0.9% sodium chloride)	• Contact the manufacturer for information on the stability of the vaccine. If the manufacturer does not have information to support the stability of the vaccine, repeat the dose immediately (no minimum interval). [§]
	• Vaccine is mixed with too little diluent	• Do not repeat dose. Inform the recipient of the potential for local and systemic adverse events.[†]
	• Vaccine is mixed with too much diluent	• Repeat dose immediately (no minimum interval). [§]
	• Single-use vial of diluent is used to mix multiple vials of vaccine	• Do not repeat dose. Inform patient of the potential for bacterial infection.
Diluent (Pfizer-BioNTech COVID-19 formulation that should not be mixed with diluent, i.e., gray cap)	• Vaccine is mixed with any diluent (i.e., any type or volume of diluent)	• Contact the manufacturer for information on the stability of the vaccine. If the manufacturer does not have information to support the stability of the vaccine, repeat the dose immediately (no minimum interval).[§]

*Do not administer the second dose until the person becomes eligible to receive vaccination (either by reaching the authorized age or if the authorization is extended to include additional age groups), even if this results in the second dose being administered after the recommended interval between doses. In addition to the minimum age, some experts suggest delaying the second dose for 8 weeks after the invalid dose based on the potential for increased reactogenicity and the rare risk of myocarditis from mRNA COVID-19 vaccine.

†If the administration error resulted in a higher-than-authorized vaccine dose, in general a subsequent dose may still be administered at the recommended interval. However, if local or systemic side effects following vaccination are clinically concerning (outside of the expected side effect profile), lead to serious adverse reactions, or are ongoing at the time of the subsequent dose, this dose might be delayed, but this decision should be assessed on a case-by-case basis.

‡ For FDA EUA dosing options for children who turn from age 4 to 5 years (Pfizer-BioNTech) and age 11 to 12 years (Pfizer-BioNTech) during vaccination, see Transitioning from a younger to older age group. If the dosing is in accordance with the FDA EUA, it is not considered an error and VAERS reporting is not indicated.

§Some experts suggest delaying the repeat dose for 8 weeks after the invalid dose based on the potential for increased reactogenicity and the rare risk of myocarditis from mRNA COVID-19 vaccine, particularly in groups at increased risk for myocarditis (e.g., males ages 12–39 years). Individual risk for COVID-19 and the likelihood for an adverse event following vaccination should be taken into consideration when recommending a longer interval. It is acceptable to administer the repeat dose at an interval earlier than 8 weeks as long as the interval is not sooner than the minimal interval noted in this table.

¶For the purpose of the public health definition of fully vaccinated, primary series doses administered with an interval error prior to October 25, 2021 do not need to be repeated.

For the purpose of the public health definition of up to date, first booster doses administered with an interval error prior to March 30, 2022 do not need to be repeated.

#Vaccine doses administered up to 4 days before the minimum interval may be counted and do not need to be repeated.

**As of the date of this update, current manufacturer contact information is:

- Pfizer: 1-877-VAX-CO19 (1-877-829-2619)
- Moderna: 1-866-MODERNA (1-866-663-3762); medinfo@modernatx.com
- Janssen: US Toll Free: 1-800-565-4008; US Toll: 1-908-455-9922

Please see the package inserts and EUA provider factsheets for the most up-to-date manufacturer information.

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Appendix D. Schedule guidance for people who are moderately or severely immunocompromised

D.1. People who are moderately or severely immunocompromised and initiate a Janssen COVID-19 Vaccine primary series

COVID-19 vaccination history	And	Then	Next dose due
1 dose	The dose was Janssen COVID-19 Vaccine	Administer a second (additional) dose using an mRNA vaccine at least 28 days after the 1st dose • Pfizer: 0.3mL, or • Moderna 0.5mL (red cap)	Administer a booster dose at least 2 months after the 2nd dose.* • Pfizer: 0.3mL, or • Moderna: 0.25mL (red cap) or 0.5 mL (blue cap), or • Janssen: 0.5mL (mRNA is preferred over Janssen) Administer a second booster dose if eligible.†
2 doses	Both doses are Janssen COVID-19 Vaccine	Administer a third (additional) dose using an mRNA vaccine at least 2 months after the 2nd dose • Pfizer: 0.3mL, or • Moderna: 0.5mL (red cap)	Administer a second booster dose if eligible.†
	1 dose of Janssen COVID-19 Vaccine and 1 dose of an mRNA COVID-19 vaccine (given as booster dose, i.e., Pfizer 0.3mL or Moderna 0.25mL [red cap], or Moderna 0.5mL [blue cap]) ‡	Administer a third (additional) dose using an mRNA vaccine at least 2 months after the 2nd dose • Pfizer: 0.3mL, or • Moderna: 0.5mL (red cap)	Administer a second booster dose if eligible.†
	1 dose of Janssen COVID-19 Vaccine and 1 dose of an mRNA COVID-19 vaccine (given as additional dose, i.e., Pfizer 0.3mL or Moderna 0.5mL [red cap]) ‡	Administer a booster dose of any COVID-19 vaccine 2 months after the 2nd dose* • Pfizer: 0.3mL, or • Moderna: 0.25mL (red cap) or 0.5mL (blue cap), or • Janssen: 0.5mL (mRNA is preferred over Janssen)	Administer a second booster dose if eligible.†

*mRNA vaccines are preferred.

† For information on who is eligible for a second booster dose, see guidance for people who are moderately or severely immunocompromised.

‡ When reviewing vaccination history, doses of the Moderna COVID-19 Vaccine received prior to February 7, 2022 should be considered to have been the booster dosage (0.25 mL; 50 µg).

D.2. People who are moderately or severely immunocompromised and initiate an mRNA COVID-19 vaccine primary series

D.2. People who are moderately or severely immunocompromised and initiate an mRNA COVID-19 vaccine primary series

COVID-19 vaccination history	And	Then*†	Next dose due*†
1 dose	The dose was an mRNA vaccine	Administer a second primary series dose of the same mRNA vaccine • 3 weeks after the first dose, if Pfizer-BioNTech • 4 weeks after the first dose, if Moderna	Administer a third primary series dose of the same mRNA vaccine • At least 4 weeks after the second dose for most people • At least 8 weeks after the second dose if ages 6 months–4 years and receiving Pfizer-BioNTech vaccine Then, administer a booster dose at least 3 months after the third dose if eligible. Administer a second booster dose if eligible.
2 doses	The 2 doses are the same mRNA vaccine (both Pfizer-BioNTech or both Moderna)	Administer a third primary series dose of the same mRNA vaccine • At least 4 weeks after the second dose for most people • At least 8 weeks after the second dose if ages 6 months–4 years and receiving Pfizer-BioNTech vaccine	Administer a booster dose at least 3 months after the third primary series dose if eligible. Administer a second booster dose if eligible.
	The 2 doses are different mRNA vaccines (1 dose Pfizer-BioNTech and 1 dose Moderna)	Administer a third primary series dose of either mRNA vaccine • At least 4 weeks after the second dose for most people • At least 8 weeks after the second dose if ages 6 months–4 years	Administer a booster dose at least 3 months after the third primary series dose if eligible. Administer a second booster dose if eligible.
	The 2 doses are different types of vaccines (1 dose of an mRNA vaccine and 1 dose of Janssen)	This is considered a Janssen COVID-19 Vaccine primary series. Administer an additional dose of Pfizer-BioNTech or Moderna at least 28 days after the Janssen COVID-19 Vaccine.	Administer a booster dose at least 2 months after the additional mRNA vaccine dose. Administer a second booster dose if eligible.
3 doses	3 primary series doses of an mRNA vaccine (includes 3 doses of the same mRNA vaccine or a mixed mRNA vaccine series)	Administer a booster dose at least 3 months after the last dose given if eligible.	Administer a second booster dose if eligible.
	2 primary series doses of an mRNA vaccine and 1 booster dose of any vaccine	Administer a third primary dose (fourth total dose) of an mRNA vaccine at least 3 months after the last dose given.	Administer a second booster dose if eligible.

*mRNA vaccines are preferred for all primary doses and the first booster dose; only mRNA vaccines can be used for the second booster dose.

† For information on who is eligible for booster dose(s), see guidance for people who are moderately or severely immunocompromised.

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Appendix E. Triage of people with a history of allergies or allergic reactions

CONTRAINDICATION TO COVID-19 VACCINATION	PRECAUTION TO COVID-19 VACCINATION	MAY PROCEED WITH COVID-19 VACCINATION

CONTRAINDICATION TO COVID-19 VACCINATION	PRECAUTION TO COVID-19 VACCINATION	MAY PROCEED WITH COVID-19 VACCINATION
History of the following: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of a COVID-19 vaccine[1,2] • Known (diagnosed) allergy to a component of a COVID-19 vaccine[1]	**Among people without a contraindication, a history of:** • Any immediate allergic reaction[3] to other vaccines (non-COVID-19) or injectable therapies[4] • Non-severe, immediate (onset <4 hours) allergic reaction[2] after a previous dose of COVID-19 vaccine[6] Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 Vaccine, and vice versa[5]	**Among people without a contraindication or precaution, a history of:** • Allergy (including anaphylaxis) to oral medications (including the oral equivalent of an injectable medication) • History of food, pet, insect, venom, environmental, latex, etc., allergies, including anaphylaxis • Family history of allergies
Actions: • Do not vaccinate • Consider referral to allergist-immunologist • Consider other vaccine alternative if age appropriate[1,5]	**Actions:** • Risk assessment • 30-minute observation period if vaccinated (see footnotes 5 and 6 for information on vaccination setting) • Consider referral to allergist-immunologist	**Actions:** • 30-minute observation period: people with history of anaphylaxis (due to any cause) • 15-minute observation period: all other people

Note: This table is specific to allergy-related contraindications and precautions and is not inclusive of all COVID-19 vaccine contraindications and precautions.

[1] COVID-19 vaccine-specific FDA fact sheets and U.S. COVID-19 Vaccine Product Information can be consulted for a full list of ingredients. People with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna). However, some of these people may be able to receive Janssen COVID-19 Vaccine after a detailed risk assessment and possibly allergy testing (see footnote 5 below).

[2] Severe allergic reactions include:

- Possible anaphylaxis, a progressive life-threatening reaction that typically includes urticaria but also with other symptoms such as wheezing, difficulty breathing, or low blood pressure
- Any angioedema affecting the airway (i.e., tongue, uvula, or larynx)
- Diffuse rash which also involves mucosal surfaces (e.g., Stevens-Johnson Syndrome)

Non-severe allergic reactions may include:

- Urticaria (hives) beyond the injection site
- Angioedema (visible swelling) involving lips, facial skin, or skin in other locations. NOTE: Any angioedema affecting the airway (i.e., tongue, uvula, or larynx) would NOT be in this category and is considered a severe allergic reaction

[3] Immediate allergic reaction to a vaccine or injectable therapy is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

[4] People with a history of an immediate allergic reaction to a non-COVID-19 vaccine or injectable therapy that contains multiple components, one or more of which is a component of a COVID-19 vaccine, but it is unknown which component elicited the allergic reaction, have a precaution to vaccination with that COVID-19 vaccine. These people may benefit from consultation with an allergist-immunologist who can perform a more detailed risk assessment for COVID-19 vaccine receipt and possibly allergy testing.

[5] Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 Vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur. People with a contraindication to mRNA COVID-19 vaccines (including due to a known allergy to PEG) have a precaution to Janssen COVID-19 Vaccine. Among people who received a first mRNA COVID-19 dose but for whom the second dose is contraindicated, consideration may be given to vaccination with Janssen COVID-19 Vaccine (administered at least 28 days after the mRNA COVID-19 dose). People with a contraindication to Janssen COVID-19 Vaccine (including due to a known allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines. For people with these precautions, referral to an allergist-immunologist should be considered. Healthcare professionals and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project. In patients with these precautions, vaccination should only be undertaken in an appropriate setting under the supervision of a healthcare professional experienced in the management of severe allergic reactions.

[6] For people with a history of an immediate, non-severe allergic reaction after an mRNA COVID-19 vaccine, vaccination with a subsequent dose of either of the mRNA COVID-19 vaccines should only be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Similarly, for people with a history of an immediate, non-severe allergic reaction after Janssen COVID-19 Vaccine, vaccination with a subsequent dose of Janssen vaccine should only be undertaken under the supervision of a health care provider experienced in the management of severe allergic reactions. Administering the other vaccine type is another option; this can be done with a 30-minute observation period in a usual COVID-19 vaccination setting.

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References and Previous Updates

References

- The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine — United States, December 2020
- The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Moderna COVID-19 Vaccine — United States, December 2020
- The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID-19 Vaccine — United States, February 2021
- Updated Recommendations from the Advisory Committee on Immunization Practices for Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients—United States, April 2021
- The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Adolescents Aged 12–15 years — United States, May 2021
- Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021
- Use of COVID-19 Vaccines After Reports of Adverse Events Among Adult Recipients of Janssen (Johnson & Johnson) and mRNA COVID-19 Vaccines (Pfizer-BioNTech and Moderna): Update from the Advisory Committee on Immunization Practices — United States, July 2021
- Use of Pfizer-BioNTech COVID-19 Vaccine in Persons Aged ≥16 Years: Recommendations of the Advisory Committee on Immunization Practices — United States, September 2021
- The Advisory Committee on Immunization Practices' Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines — United States, 2021
- The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Children Aged 5–11 Years — United States, November 2021
- Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine: Updated Interim Recommendations from the Advisory Committee on Immunization Practices — United States, December 2021

- The Advisory Committee on Immunization Practices' Recommendation for Use of Moderna COVID-19 Vaccine in Adults Aged ≥18 Years and Considerations for Extended Intervals for Administration of Primary Series Doses of mRNA COVID-19 Vaccines — United States, February 2022
- Pfizer-BioNTech COVID-19 Vaccine Fact Sheet for Healthcare Providers (fda.gov)
- Moderna COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers (fda.gov)
- Janssen COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers (fda.gov)
- Emergency Use Instructions for Healthcare Providers: Pfizer-BioNTech COVID-19 Vaccine for Primary, Additional, and/or Booster Doses (cdc.gov)
- Emergency Use Instructions for Healthcare Providers: Moderna COVID-19 Vaccine for Primary, Additional, and/or Booster Doses (cdc.gov)
- ACIP General Best Practice Guidelines for Immunization
- Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination

Previous Updates

May 20, 2022

- New guidance for use of a Pfizer-BioNTech COVID-19 Vaccine booster dose in children ages 5–11 years
- Updated guidance that the following people should receive a second COVID-19 booster dose:
  - People ages 12 years and older who are moderately or severely immunocompromised
  - People ages 50 years and older
- Updated guidance for people who are moderately or severely immunocompromised and are treated with B-cell-depleting therapies
- Clarification of COVID-19 vaccination guidance for multisystem inflammatory syndrome in children (MIS-C) and adults (MIS-A)
- Updated guidance for primary series vaccination after SARS-CoV-2 infection

April 21, 2022

- Added considerations for the option to receive a second COVID-19 vaccine booster dose
- Updated guidance for COVID-19 vaccination after SARS-CoV-2 infection

March 30, 2022

- Added guidance that people ages 12 years and older who are moderately or severely immunocompromised may choose to receive a second booster dose using an mRNA COVID-19 vaccine at least 4 months after the first booster dose
- Added guidance that adults ages 50 years and older who are not moderately or severely immunocompromised may choose to receive a second booster dose using an mRNA COVID-19 vaccine at least 4 months after the first booster dose
- Added guidance that people ages 18–49 years who are not moderately or severely immunocompromised and who received Janssen COVID-19 Vaccine as both their primary series dose and booster dose may receive a second booster dose using an mRNA COVID-19 vaccine at least 4 months after the first Janssen booster dose
- Further clarification of safety issues including those related to multisystem inflammatory syndrome in children (MIS-C) and adults (MIS-A) and myocarditis
- Updated information on the availability of Moderna COVID-19 Vaccine supplied in a vial with a red cap (0.25 mL dosage volume) and Moderna COVID-19 Vaccine supplied in a vial with a blue cap (0.5 mL dosage volume) for administration of a 50 µg booster dose.

February 22, 2022

- Added considerations for an 8-week interval between the first and second doses of a primary mRNA vaccine schedule

February 11, 2022

- Updated guidance for moderately or severely immunocompromised people
    - Clarification of existing recommendation to receive a 3-dose mRNA vaccine primary series followed by a booster dose for a total of 4 doses
    - New guidance to shorten the interval between completion of the mRNA vaccine primary series and the booster dose to at least 3 months (instead of 5 months)
    - New guidance for those who received the Janssen COVID-19 Vaccine primary series to receive an additional dose and a booster dose, for a total of 3 doses to be up to date
- Updated guidance that it is no longer necessary to delay COVID-19 vaccination following receipt of monoclonal antibodies or convalescent plasma
- Updated guidance on receiving a booster dose if vaccinated outside the United States
- Updated contraindication and precaution section to include history of myocarditis or pericarditis after an mRNA COVID-19 vaccine as a precaution
- Reorganized and condensed multiple sections

January 6, 2022

- Updated guidance for use of Pfizer-BioNTech COVID-19 Vaccine as a booster in people ages 12–17 years
- Updated guidance for administration of a COVID-19 vaccine booster dose at least 5 months after completion of an mRNA vaccine (Pfizer-BioNTech or Moderna) primary series
- Updated guidance for use of an additional primary dose for moderately or severely immunocompromised people ages 5–11 years who received a Pfizer-BioNTech vaccine primary series
- Updated recommendations for people who received COVID-19 vaccines outside the United States that are not FDA-authorized or approved

December 23, 2021

- Updated information about a second formulation of Pfizer-BioNTech COVID-19 Vaccine that is authorized for use in persons ages 12 years and older
- Updated information on vaccinating people during quarantine after a known SARS-CoV-2 exposure or during COVID-19 outbreaks
- Update to alert providers of possible false positive Rapid Plasma Reagin (RPR; non-treponemal) test results in some people after COVID-19 vaccines
- Updated information on vaccine administration errors and deviations

December 17, 2021

- Updated guidance on use of Janssen (Johnson & Johnson) COVID-19 Vaccine

December 10, 2021

- Updated recommendations for receipt of a COVID-19 vaccine booster dose

November 19, 2021

- Updated guidance for COVID-19 booster doses in recipients of mRNA COVID-19 vaccines

November 17, 2021

- Updated guidance in section on People who received COVID-19 vaccine outside the United States
- Updated guidance in section on People who received COVID-19 as part of a clinical trial

November 3, 2021

- Recommendations and clinical guidance for use of Pfizer-BioNTech COVID-19 Vaccine in children aged 5-11 years including updated section on Vaccination of children and adolescents

- Updated guidance on COVID-19 vaccine dosing and schedule
- Updated guidance for myocarditis and pericarditis after mRNA COVID-19 vaccination in new section on Considerations for mRNA COVID-19 vaccines: Pfizer-BioNTech and Moderna
- New guidance for people who received passive antibody products in section on COVID-19 vaccination and SARS-CoV-2 infection
- Updated guidance in section on People who received COVID-19 vaccine outside the United States
- Updated guidance in section on People who received COVID-19 as part of a clinical trial in the United States
- Updated guidance on Considerations for COVID-19 vaccination in moderately and severely immunocompromised people
- Updated guidance in section on Contraindications and precautions
- Updated Table in Appendix A: Vaccine administration errors and deviations
- Updated Appendix B: Triage of people with a history of allergies or allergic reactions
- Updated Appendix C: Ingredients included in COVID-19 vaccines
- Updated Appendix D: Potential characteristics of allergic reactions, vasovagal reactions, and vaccine side effects following COVID-19 vaccination

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 (MIS-A); 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.

September 27, 2021

- New section on Considerations for use of a Pfizer-BioNTech COVID-19 Vaccine booster dose after completion of a Pfizer-BioNTech primary vaccine series.

September 15, 2021

- Updated information in the section on COVID-19 vaccination and SARS-CoV-2 infection.
- Updated information in the section on Vaccinating people with a known COVID-19 exposure or during COVID-19 outbreaks.
- New section on Vaccinating people receiving medical care unrelated to COVID-19.
- New section on Vaccinating people undergoing SARS-CoV-2 screening.

August 31, 2021

- New Advisory Committee on Immunization Practices (ACIP) recommendation for use of the U.S. Food and Drug Administration (FDA)-approved Pfizer-BioNTech (COMIRNATY) COVID-19 Vaccine in persons aged ≥16 years.
- Updated information in Key points to reflect currently available evidence.
- Updated information on COVID-19 vaccines in the Background section.
- Updated information in the section on Considerations for use of an additional dose of COVID-19 vaccine following a

- Updated information in the section on considerations for use of an additional dose of COVID-19 vaccine following a primary vaccine series.
- Updated laboratory testing information on timing of immune-based tests for tuberculosis infection in relation to COVID-19 vaccine administration.

August 25, 2021

- New section on people vaccinated for COVID-19 as part of a clinical trial in the United States.
- Updated considerations for use of an additional mRNA COVID-19 vaccine dose after an initial 2-dose COVID-19 mRNA vaccine series for immunocompromised people.

August 13, 2021

- New section on considerations for use of an additional dose of COVID-19 vaccine.
- New section on considerations for use of an additional mRNA COVID-19 vaccine dose after an initial 2-dose mRNA COVID-19 primary vaccine series for immunocompromised people.

August 11, 2021

- Updated considerations for people who are pregnant, lactating, trying to get pregnant now, or might become pregnant in the future.

August 6, 2021

- Updated considerations for COVID-19 vaccination in people with a history of Guillain-Barré syndrome.
- Updated information on vaccine administration errors and deviations in Appendix A (Table).

July 16, 2021

- Updated considerations regarding mRNA vaccine dosing intervals.
- Updated considerations for immunocompromised people.

July 2, 2021

- New section on considerations for use of mRNA COVID-19 vaccines in people with a history of myocarditis or pericarditis added to considerations for vaccination of people with certain underlying medical conditions.
- New information on the occurrence of myocarditis or pericarditis following vaccination with mRNA COVID-19 vaccines added to patient counseling.

June 1, 2021

- Information on cases of myocarditis and pericarditis occurring after mRNA COVID-19 vaccination, particularly in adolescents and young adults.
- Information on the efficacy of the Pfizer-BioNTech COVID-19 Vaccine in adolescents aged 12–15 years in patient counseling section.
- Updated data on local and systemic symptoms following vaccination with mRNA COVID-19 vaccines in patient counseling section.
- Clarification in contraindications and precautions and Appendix B of guidance for people with a history of an immediate allergic reaction to a vaccine or injectable therapy that contains a component also contained in a COVID-19 vaccine.
- Updated list of ingredients in COVID-19 vaccines (i.e., lack of metals) in Appendix C.
- Correction of footnote numbering.

May 14, 2021

- Updated information for authorized age groups to include vaccination of adolescents aged 12–15 years with Pfizer-BioNTech COVID-19 Vaccine.

- Updated information on coadministration of COVID-19 vaccines with other vaccines.
- A new section on persons with a history of multisystem inflammatory syndrome added to considerations for vaccination of people with certain underlying medical conditions.
- Updated recommendation for timing of COVID-19 vaccine administration in persons with a history of heparin-induced thrombocytopenia.
- Updated information on vaccination of children and adolescents.

April 27, 2021

- The Advisory Committee on Immunization Practices' updated interim recommendation for the use of the Janssen (Johnson & Johnson) COVID-19 Vaccine.
- Clarification that COVID-19 vaccination is recommended for all people 16 years and older added to key points and vaccine administration.
- Updated information about the Janssen COVID-19 Vaccine added to background.
- Requirements to be considered fully vaccinated added to vaccine administration and interchangeability of COVID-19 vaccine products.
- New section added for people vaccinated with COVID-19 vaccines not authorized in the United States.
- Clarification on COVID-19 vaccination and SARS-CoV-2 infection. People with prolonged post-COVID-19 symptoms should be offered COVID-19 vaccination.
- New section added on antiviral therapy and COVID-19 vaccination.
- Information on requesting a consultation from the Clinical Immunization Safety Assessment COVIDvax project added to considerations for vaccination of people with certain underlying medical conditions.
- New section added on considerations for use of the Janssen COVID-19 Vaccine in certain populations.
- Updated information and recommendations for vaccination of pregnant or lactating people.
- Updated recommendations for vaccination of children and adolescents.
- Updated information related to axillary lymphadenopathy added to patient counseling for mRNA COVID-19 vaccines.
- Updated information on the Janssen COVID-19 Vaccine added to patient counseling.
- Updated recommendations related to contraindications (polysorbate allergy) and precautions (most people with a precaution can and should be administered vaccine) for COVID-19 vaccines.

April 16, 2021

- Recommended pause in the use of Janssen (Johnson & Johnson) COVID-19 Vaccine.
- Recommendations for clinicians related to occurrence of cerebral venous sinus thrombosis (CVST) with thrombocytopenia after receipt of Janssen COVID-19 Vaccine.

March 5, 2021

- Public health recommendations for vaccinated people have been moved to: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html.

March 3, 2021

- Clinical considerations added for use of Janssen (Johnson & Johnson) COVID-19 Vaccine.
- Updated recommendations for fully vaccinated people who subsequently develop COVID-19.
- Updated recommendations related to COVID-19 vaccination timing for immunocompromised people.
- Updated contraindications and precautions to mRNA COVID-19 vaccines.
- Updated information on interpretation of SARS-CoV-2 antibody test results after vaccination.

February 10, 2021

- New recommendations for preventing, reporting, and managing mRNA COVID-19 vaccine administration errors (Appendix A)

(Appendix A).

- Clarification on contraindications and precautions. People with a known (diagnosed) allergy to PEG, another mRNA vaccine component, or polysorbate, have a contraindication to vaccination. People with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is PEG, another mRNA vaccine component or polysorbate, but in whom it is unknown which component elicited the immediate allergic reaction have a precaution to vaccination.
- Updated information on delayed, local injection-site reactions after the first mRNA vaccine dose. These reactions are neither a contraindication nor a precaution to the second dose.
- Updated quarantine recommendations for vaccinated people. Fully vaccinated people who meet criteria will no longer be required to quarantine following an exposure to someone with COVID-19. Additional considerations for patients and residents in healthcare settings are provided.
- Additional information and updated recommendations for testing for TB infection. TB testing can be done before or at the same time as mRNA COVID-19 vaccination, or otherwise delayed for ≥4 weeks after the completion of mRNA COVID-19 vaccination.

Page last reviewed: June 21, 2022