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

Summary of recent changes (last updated July 20, 2022):

- Guidance for primary series vaccination using Novavax COVID-19 Vaccine in adults ages 18 years and older
- Updated guidance on COVID-19 vaccination and myocarditis and pericarditis

Reference Materials

- Summary Document for Interim Clinical Considerations (Updated 6/24/2022)
- Interim COVID-19 Immunization Schedule (Updated 6/24/2022)
- At-A-Glance COVID-19 Vaccination Schedule (Updated 7/20/2022)
- Moderna COVID-19 Vaccine for Children who Transition from a Younger to Older Age Group
- Pfizer-BioNTech for Children who Transition from a Younger to Older Age Group

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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).
- For primary series vaccination, mRNA COVID-19 vaccines (i.e., Moderna and Pfizer-BioNTech) and Novavax COVID-19 Vaccine are recommended. For booster vaccination, mRNA vaccines are recommended; recommendations for booster dose(s) vary based on age, primary series product, and immunocompetence. Janssen COVID-19 Vaccine should only be used in limited situations.
- 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 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

Four COVID-19 vaccines, categorized into three vaccine types, 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):

- Two are mRNA vaccines
  - Moderna COVID-19 Vaccine/SPIKEVAX (hereafter referred to as Moderna in this document) *(1)*
  - Pfizer-BioNTech COVID-19 Vaccine/COMIRNATY (hereafter referred to as Pfizer-BioNTech in this document) *(2)*
- Novavax COVID-19 Vaccine, Adjuvanted (hereafter referred to as Novavax in this document), is a protein subunit vaccine
- Janssen (Johnson & Johnson) COVID-19 Vaccine (hereafter referred to as Janssen in this document), is an adenovirus vector vaccine

None of the currently FDA-approved or FDA-authorized COVID-19 vaccines are live-virus vaccines.

For primary series vaccination, three COVID-19 vaccines (listed in alphabetical order by manufacturer), are recommended: Moderna, Novavax, and Pfizer-BioNTech. For booster vaccination, Moderna and Pfizer-BioNTech are recommended and must be used for the second booster dose. A person's eligibility for a booster dose(s) depends on age, primary series product, and immunocompetence.

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 Janssen COVID-19 Vaccine (see Patient counseling and Safety considerations for Janssen COVID-19 Vaccine). However, offering 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.

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).

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.

There is currently no FDA-approved or FDA-authorized COVID-19 vaccine for children younger than age 6 months.

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 extended intervals for COVID-19 vaccine primary series doses, 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*

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
6–11 years‡	Dark blue	Purple	No	50 µg	0.5 mL	NA	NA
12–17 years	Red	Light blue	No	100 µg	0.5 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

Novavax

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	Royal blue	No color	No	5 µg rS and 50 µg of Matrix-M™ adjuvant	0.5 mL	NA	NA

Pfizer-BioNTech

Age indication	Vaccine vial cap color	Label border color	Dilution required	Primary series	Booster doses†

Age indication	Vaccine vial cap color	Label border color	Dilution required	Primary series		Booster doses†	
				Dose	Injection volume	Dose	Injection volume
				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

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	No color	No	5×10^{10} viral particles	0.5 mL	5×10^{10} viral particles	0.5 mL

Abbreviation: NA = not authorized; rS = recombinant spike protein

*Illustrations of the different vaccine vial cap and label border colors are available from FDA for Moderna and Pfizer-BioNTech COVID-19 vaccines. Additional product-specific information is available 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, Moderna and Pfizer-BioNTech can be used as a booster dose. Currently, Novavax COVID-19 Vaccine is not authorized for booster vaccination.

‡Moderna COVID-19 Vaccine supplied in a vial with a dark blue cap and a label with a teal border stating "Age 6y through 11y" is currently not available. Moderna COVID-19 Vaccine supplied in a vial with a dark blue cap and a label with a purple border stating "BOOSTER DOSES ONLY Booster dose: 0.5mL " is FDA-authorized for use in children ages 6–11 years as a primary series 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 may be 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.

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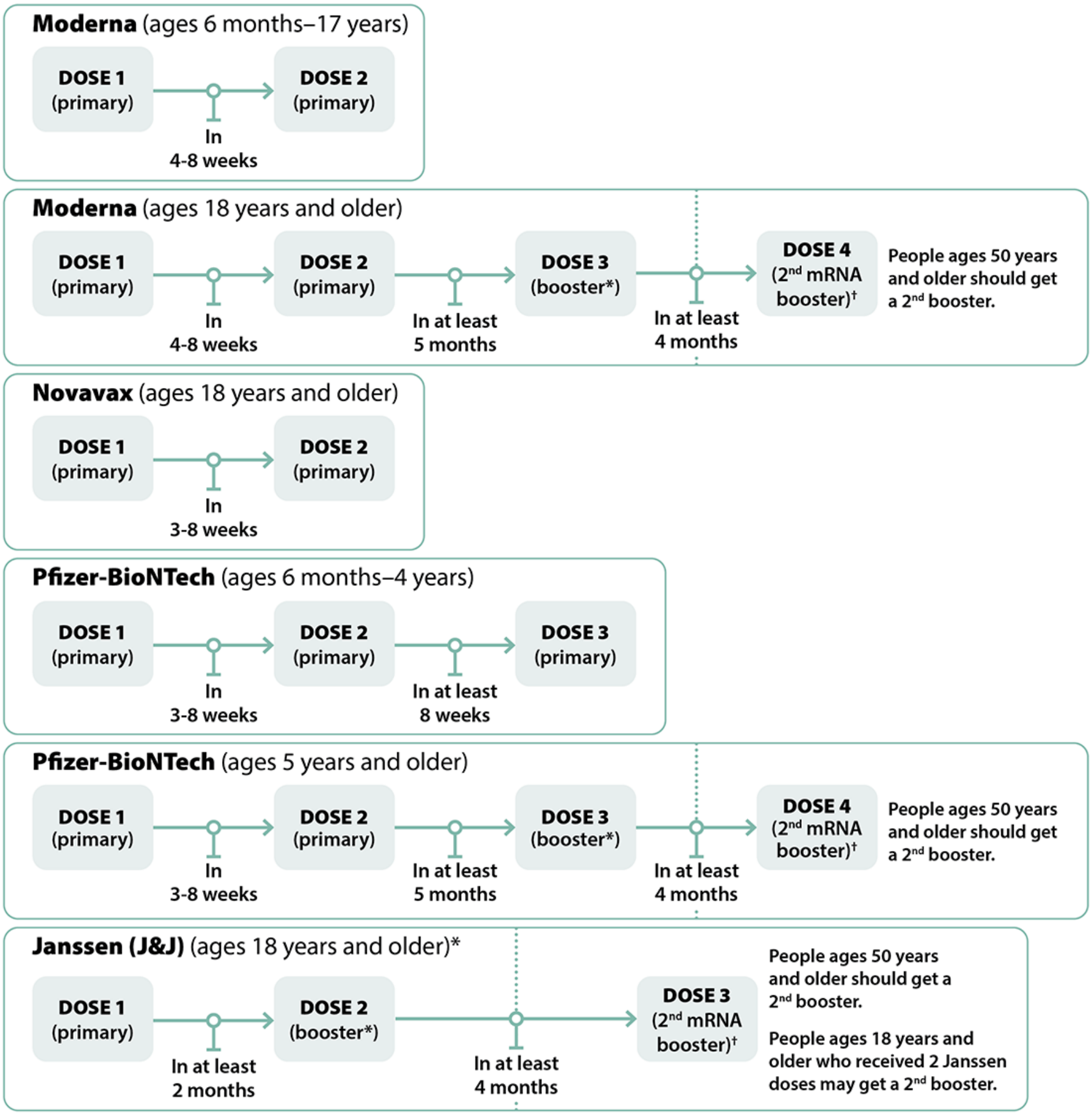
COVID-19 vaccination guidance for people who are **not** moderately or severely immunocompromised

Overview

COVID-19 Vaccination Schedule for People who are **NOT** Moderately or Severely Immunocompromised



*Age-appropriate mRNA (Moderna or Pfizer-BioNTech) and Novavax vaccines are recommended for primary vaccination. For booster vaccination, mRNA vaccines are recommended. Janssen COVID-19 Vaccine should only be used in limited situations for primary or booster vaccination. 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 People who are NOT Moderately or Severely Immunocompromised

For primary series vaccination, Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines are recommended. For booster vaccination, Moderna and Pfizer-BioNTech are recommended; recommendations for booster dose(s) vary based on age, primary series product, and immunocompetence. Janssen COVID-19 Vaccine should only be used in limited situations and cannot be used for the second booster dose.

The same 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
Moderna	6 months–5 years	2	2	NA	4–8 weeks	NA	NA
Moderna	6–11 years	2	2	NA	4–8 weeks	NA	NA
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

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
Moderna	12–17 years	2	2	NA	4–8 weeks	NA	NA
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
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
Novavax	18 years and older	2	2	NA	3–8 weeks	NA	NA
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
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

*For primary series vaccination, Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines are recommended. Janssen COVID-19 Vaccine should only be used in limited situations.

†For booster vaccination, Moderna and Pfizer-BioNTech are recommended and must be used for the second booster dose. Janssen COVID-19 Vaccine should only be used in limited situations. Currently, a booster dose using any COVID-19 vaccine is not authorized for people ages 6–17 years who receive a Moderna primary series or people ages 18 years and older who receive a Novavax primary series.

‡An **8-week** interval between the first and second primary series doses of Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines may be optimal for some people ages 6 months–64 years, especially for males ages 12–39 years, as it may reduce the small risk of myocarditis/pericarditis associated with these vaccines. A **shorter interval** (3 weeks for Novavax and 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

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 using any COVID-19 vaccine is not authorized for children in this age group who receive a Moderna primary series.
- Children ages 6–11 years: Should receive a 2-dose primary series separated by 4–8 weeks. Currently, a booster dose using any COVID-19 vaccine is not authorized for children in this age group who receive a Moderna primary series.

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 dose using any COVID-19 vaccine is not authorized for children in this age group who receive a Pfizer-BioNTech primary series.
- 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.

Schedule: ages 12 through17 years

Moderna COVID-19 Vaccine

- Adolescents ages 12–17 years: Should receive a 2-dose primary series separated by 4–8 weeks. Currently, a booster dose using any COVID-19 vaccine is not authorized for adolescents in this age group who receive a Moderna primary series.

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 a Pfizer-BioNTech primary series.

Schedule: ages 18 years and older

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.

Novavax COVID-19 Vaccine

- Adults ages 18 years and older: Should receive a 2-dose primary series separated by 3–8 weeks. Currently, a booster dose using any COVID-19 vaccine is not authorized for adults in this age group who receive a Novavax primary series.

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.

Janssen COVID-19 Vaccine

Janssen COVID-19 Vaccine should only be used in limited situations and cannot be used as a second booster dose; 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 using an mRNA vaccine 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 extended intervals for COVID-19 vaccine primary series doses

An 8-week interval between the first and second primary series doses of Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines may be optimal for some people as it may reduce the small risk of myocarditis and/or pericarditis associated with these COVID-19 vaccines.

COVID-19 vaccines are FDA-approved or FDA-authorized for a 3-week (Novavax and Pfizer-BioNTech) or 4-week (Moderna) 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).

Moderna, Novavax, and Pfizer-BioNTech 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, an elevated risk for myocarditis and/or pericarditis has been observed among mRNA COVID-19 vaccine recipients, particularly in males ages 12–39 years (see COVID-19 vaccination and myocarditis and pericarditis). Cases of myocarditis and pericarditis were identified in clinical trials of Novavax COVID-19 Vaccine and through passive surveillance during post-authorization use outside the United States.

The risk of vaccine-associated myocarditis and/or pericarditis might be reduced by extending the interval between the first and second primary series doses of these vaccines. Some studies in adolescents (ages 12–17 years) and adults have shown the small risk of myocarditis and/or pericarditis 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 between the first and second primary series doses may be optimal for some people as it may reduce the small risk of myocarditis and/or pericarditis associated with Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines.

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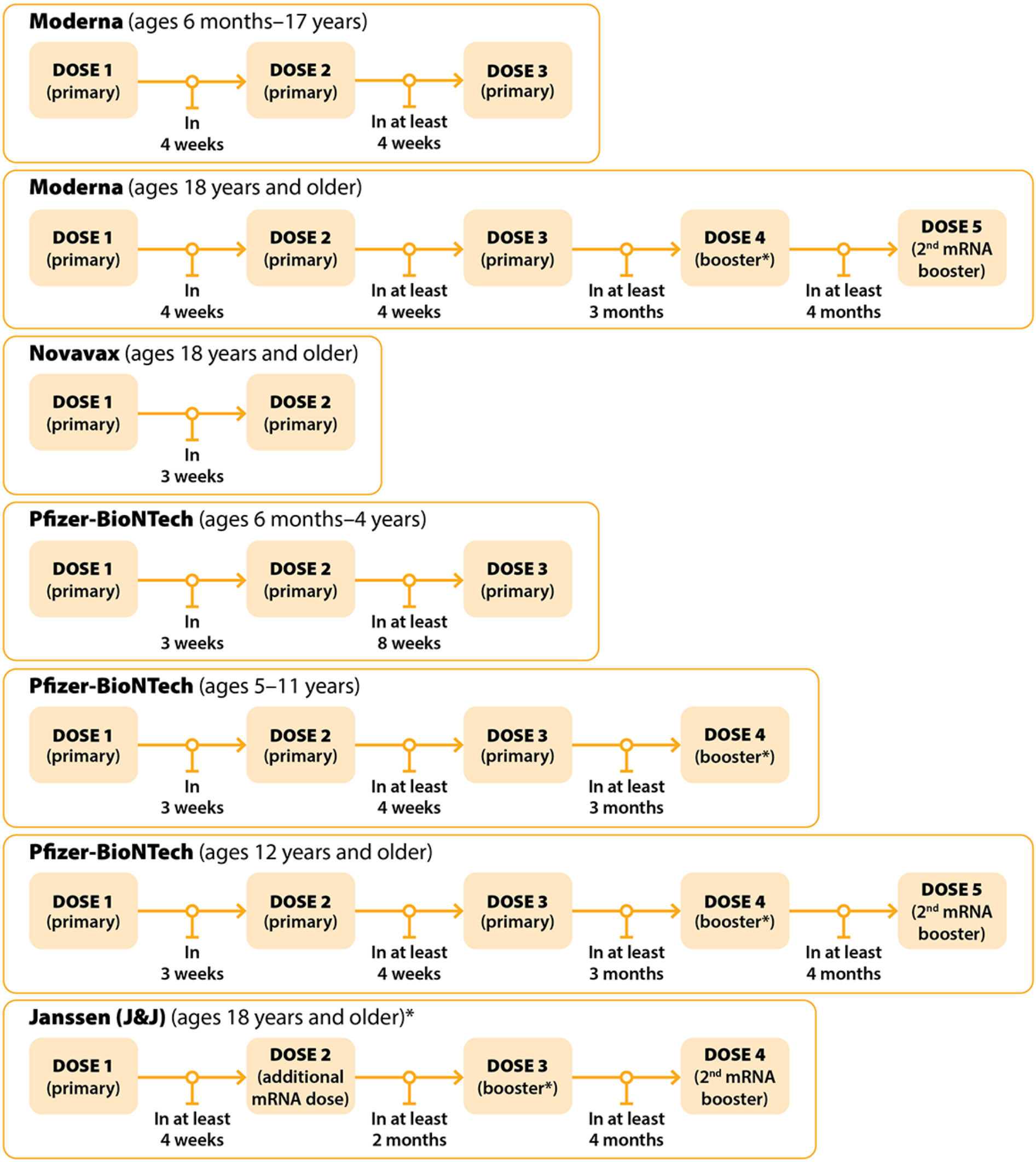
COVID-19 vaccination guidance for people who are moderately or severely immunocompromised

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 People who received SARS-CoV-2 antibody-based products for information on timing of administration of tixagevimab/cilgavimab (EVUSHELD™) in relation to COVID-19 vaccination.

Overview

COVID-19 Vaccination Schedule for People who **ARE** Moderately or Severely Immunocompromised



*Age-appropriate mRNA (Moderna or Pfizer-BioNTech) and Novavax vaccines are recommended for primary vaccination. For booster vaccination, mRNA vaccines are recommended. Janssen COVID-19 Vaccine should only be used in limited situations for primary or booster vaccination. 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 vaccination, Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines are recommended. For booster vaccination, Moderna and Pfizer-BioNTech are recommended; recommendations for booster dose(s) vary based on age, primary series product, and immunocompetence. Janssen COVID-19 Vaccine should only be used in limited situations and cannot be used for the second booster dose. The same 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.

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 that dose. 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
Moderna	6 months–5 years	3	3	NA	4 weeks	At least 4 weeks	NA	NA
Moderna	6–11 years	3	3	NA	4 weeks	At least 4 weeks	NA	NA
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

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
Moderna	12–17 years	3	3	NA	4 weeks	At least 4 weeks	NA	NA
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
Moderna	18 years and older	5	3	2	4 weeks	At least 4 weeks	At least 3 months	At least 4 months
Novavax	18 years and older	2	2	NA	3 weeks	NA	NA	NA
Pfizer-BioNTech	18 years and older	5	3	2	3 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	At least 4 weeks	At least 2 months	At least 4 months	NA

Abbreviations: Use...

Abbreviation: NA = not authorized

*For primary series vaccination, Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines are recommended; Janssen COVID-19 Vaccine should only be used in limited situations.

†For booster vaccination, Moderna and Pfizer-BioNTech are recommended and must be used for the second booster dose. Janssen COVID-19 Vaccine should only be used in limited situations. Currently, a booster dose using any COVID-19 vaccine is not authorized for people ages 6–17 years who receive a Moderna primary series or people ages 18 years and older who receive a Novavax primary series.

Schedule: ages 6 months through 11 years

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 using any COVID-19 vaccine is not authorized for children in this age group who receive a Moderna primary series.
- Children ages 6–11 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 using any COVID-19 vaccine is not authorized for children in this age group who receive a Moderna primary series.

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 using any COVID-19 vaccine is not authorized for children in this age group who receive a Pfizer-BioNTech primary series.
- 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.

Schedule: ages 12 through 17 years

Moderna COVID-19 Vaccine

- Adolescents ages 12–17 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 using any COVID-19 vaccine is not authorized for adolescents in this age group who receive a Moderna primary series.

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

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 booster dose at least 4 months after the first booster dose.

Novavax COVID-19 Vaccine

- Adults ages 18 years and older: Should receive a 2-dose primary series; the first and second doses are separated by 3 weeks. Currently, a booster dose using any COVID-19 vaccine is not authorized for adults in this age group who receive a Novavax primary series.

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.

Special situation: For people who inadvertently received the first booster dose before their third mRNA primary series dose, regardless of type of vaccine received as the booster dose, administer a Moderna or Pfizer-BioNTech 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 dose; 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 (Moderna [50 µg], Pfizer-BioNTech, 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 Moderna or Pfizer-BioNTech 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 mg or more 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 Moderna, Novavax, or Pfizer-BioNTech COVID-19 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 Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines outside of the FDA and CDC dosing intervals when, based on their clinical judgment, 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

Primary series

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

A mixed primary series composed of any combination of Moderna, Novavax, and Pfizer-BioNTechCOVID-19 vaccines is not authorized; data on the safety and efficacy of a mixed primary series are limited. If a mixed primary series is inadvertently administered, the series is complete, and doses do not need to be repeated.

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 the following exceptional situations, a different, age-appropriate COVID-19 vaccine may be administered to complete a primary series at a minimum interval of 28 days from the last COVID-19 vaccine dose. No VAERS report is required.

- The same vaccine is not available
- The first dose is unknown
- A person starts but is unable to complete a primary series with the same COVID-19 vaccine due to a contraindication.

People who receive Janssen COVID-19 Vaccine after a dose of another COVID-19 vaccine should be considered to have received a valid, single-dose Janssen primary series.

Booster vaccination

For booster vaccination, age-appropriate mRNA vaccines are recommended. Any age-appropriate mRNA vaccine can be used if a booster dose is FDA-approved or FDA-authorized for use in a specified population: it can be the same mRNA vaccine as the primary series (homologous booster dose) or a different mRNA vaccine (heterologous booster dose). 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. However, there are additional considerations if administering an orthopoxvirus vaccine (see below).

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, adolescents, and adults 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 may consider whether a person is behind or at risk of becoming behind on recommended vaccines and their likelihood of returning for another vaccination; their risk of becoming infected with a vaccine-preventable disease and risk for severe disease if infected; and the reactogenicity profile of the vaccines.

Orthopoxvirus vaccination: Because of the observed risk for myocarditis after receipt of ACAM2000 orthopoxvirus vaccine and mRNA (i.e., Moderna and Pfizer-BioNTech) and Novavax COVID-19 vaccines and the unknown risk for myocarditis after JYNNEOS, people, particularly adolescent or young adult males, might consider waiting 4 weeks after orthopoxvirus vaccination (either JYNNEOS or ACAM2000) before receiving a Moderna, Novavax, or Pfizer-BioNTech COVID-19 vaccine. However, if an orthopoxvirus vaccine is recommended for prophylaxis in the setting of an outbreak, orthopoxvirus vaccination should not be delayed because of recent receipt of a Moderna, Novavax, or Pfizer-BioNTech COVID-19 vaccine; no minimum interval between COVID-19 vaccination with these vaccines and orthopoxvirus vaccination is necessary.

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 product and 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.

However, FDA authorization allows for dosing options for certain age transitions for Moderna COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine as described below. Refer to Table 1 for information about age-specific vaccine products and dosages.

Moderna COVID-19 Vaccine

Children who will turn from age 5 years to 6 years: FDA authorization of the Moderna COVID-19 Vaccine allows children who will turn from age 5 years to 6 years between doses in the primary series to receive, for any primary dose: (1) the Moderna COVID-19 Vaccine product authorized for children ages 6 months–5 years or (2) the Moderna COVID-19 Vaccine product authorized for children ages 6–11 years.

Children who will turn from age 11 years to 12 years: FDA authorization of the Moderna COVID-19 Vaccine allows children who will turn from age 11 years to 12 years between doses in the primary series to receive, for any primary dose: (1) the Moderna COVID-19 Vaccine product authorized for children ages 6–11 years or (2) the Moderna COVID-19 Vaccine product authorized for people ages 12 years and older.

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 doses in the primary series to receive, for any primary 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 Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines are recommended, and that Janssen COVID-19 Vaccine should only be used in limited situations due to the risk of TTS following receipt of Janssen COVID-19 Vaccine. Those who elect to receive 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 Moderna, Novavax, and Pfizer-BioNTech 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 these 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 COVID-19 vaccination and myocarditis and pericarditis.

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/tenderness, swelling, erythema at the injection site) and systemic (e.g., fever, fatigue/malaise, 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 Moderna, Novavax, and Pfizer-BioNTech 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.

irritability/crying, sleepiness, and loss of appetite.

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.

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. For more information on the assessment and potential management of anaphylaxis, see Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination.

Potential for syncope

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.

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, Novavax, or Janssen COVID-19 Vaccine). See Appendix E for actions and additional information.
History of a known diagnosed allergy to a component of the COVID-19 vaccine	Contraindication	Do not vaccinate with a COVID-19 vaccine that contains that component.* See Appendix E for actions and additional information.
For **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 information on booster vaccination with an mRNA COVID-19 vaccine.
For **Janssen COVID-19 Vaccine**, history of an episode of an 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 or Novavax COVID-19 vaccine.
For **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 booster dose(s) using an mRNA COVID-19 vaccine.
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.
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, Novavax, 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 contraindication or precaution to the **other types of COVID-19 vaccines***.	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
History of myocarditis or pericarditis after a dose of an **mRNA or Novavax COVID-19 vaccine**	Precaution	A subsequent dose of any COVID-19 vaccine should generally be avoided. See COVID-19 vaccination and myocarditis and pericarditis for additional considerations.

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

*People with a known allergy to polysorbate have a contraindication to both Novavax and Janssen COVID-19 vaccines and a precaution to mRNA COVID-19 vaccines. In all other cases, an allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the other types.

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 vaccine who are receiving another type that has been deemed a precaution 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 one type of COVID-19 vaccine who are receiving another type that has been deemed a precaution (for example, people with a contraindication to mRNA COVID-19 vaccines who receive Novavax or 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 Preparing for the Potential Management of Anaphylaxis after 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 whether or not associated with an adverse event
- Serious adverse events , irrespective of attribution to vaccination
- Cases of Multisystem Inflammatory Syndrome (MIS) in adults and children
- 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: Moderna and Pfizer-BioNTech

In clinical trials of Moderna and Pfizer-BioNTech 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 and were rare in mRNA COVID-19 vaccine clinical trials for infants and young children. In rare instances, administration of certain combination vaccines or more than one vaccine at the same clinic visit has been associated with an increased risk of febrile seizures in infants and young children. The impact of coadministration of COVID-19 and routine vaccines on the risk of febrile seizures has not been specifically studied. CDC is monitoring for febrile seizures following COVID-19 vaccination in infants and young children.

children.

See also COVID-19 vaccination and myocarditis and pericarditis.

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Safety considerations for Novavax COVID-19 Vaccine

In clinical trials of Novavax COVID-19 Vaccine , pain/tenderness at the injection site was the most frequently reported local reaction among vaccine recipients; redness and swelling were reported less frequently. Fatigue, headache, and muscle pain were the most commonly reported systemic reactions. Most symptoms were mild to moderate in severity and resolved within 1–3 days. Overall, symptoms were more frequent in people ages 18–64 years compared to people ages 65 years and older and more frequent after dose 2 than dose 1.

See also COVID-19 vaccination and myocarditis and pericarditis.

COVID-19 vaccination and myocarditis and pericarditis

A rare risk for myocarditis and/or pericarditis has been observed following receipt of mRNA COVID-19 vaccines (i.e., Moderna and Pfizer-BioNTech) and Novavax COVID-19 Vaccine.

mRNA COVID-19 vaccines

Rare cases of myocarditis or pericarditis have occurred most frequently, although not exclusively, 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 with the highest rates observed in males ages 12–39 years.

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.

In age groups where product comparisons can be made (i.e., 18–39 years), some evidence suggests that the risk of myocarditis and pericarditis may be higher following vaccination with Moderna COVID-19 Vaccine relative to Pfizer-BioNTech COVID-19 Vaccine; however, findings are not consistent in all U.S. monitoring systems.

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; the reporting rate of myocarditis in VAERS following dose 2 of Pfizer-BioNTech marginally exceeded the background incidence rate for male children in this age group. 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.

Novavax COVID-19 Vaccine

Cases of myocarditis and pericarditis were identified in clinical trials of Novavax COVID-19 Vaccine and have also been reported during post-authorization use outside the United States. These findings suggest that an increased risk for these conditions may be present after receiving Novavax COVID-19 vaccine.

Considerations for COVID-19 vaccination

After reviewing available data on the risks and benefits, ACIP and CDC determined that the benefits (e.g., prevention of COVID-19 and its severe outcomes) outweigh the rare risk of myocarditis and/or pericarditis after receipt of Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines in all populations for which vaccination has been recommended. Extending the interval to 8 weeks between the first and second primary series doses of Moderna, Novavax, or Pfizer-BioNTech COVID-19 vaccines for some people may reduce the rare risk of vaccine-associated myocarditis and/or pericarditis (see Considerations for extended intervals for COVID-19 vaccine primary series doses).

People receiving Moderna, Novavax, and Pfizer-BioNTech 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 these 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.

Safety monitoring is ongoing to further assess the known and potential risks for myocarditis and pericarditis after COVID-19 vaccination in all age groups. CDC is also assessing the long-term effects of myocarditis in people with myocarditis after COVID-19 vaccination.

Myocarditis or pericarditis after a dose of COVID-19 vaccine

Development of myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine (i.e., Moderna or Pfizer-BioNTech) or Novavax 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 Moderna, Novavax, or Pfizer-BioNTech 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 people ages 18 years and older who choose to receive a subsequent COVID-19 vaccine, some experts advise that use of Janssen COVID-19 Vaccine be considered instead of Moderna, Novavax, or Pfizer-BioNTech COVID-19 vaccines. These people should be made aware of the associated risk of TTS; the highest risk for TTS is in females 30–49 years.

Considerations for subsequent COVID-19 vaccination may include:

- The myocarditis or pericarditis was considered unrelated to vaccination with Moderna, Novavax, or Pfizer-BioNTech (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)
- Timing of any immunomodulatory therapies; ACIP's general best practice guidelines for immunization can be consulted for more information

For myocarditis associated with MIS-C or MIS-A, see COVID-19 vaccination and MIS-C and MIS-A.

History of myocarditis or pericarditis prior to COVID-19 vaccination

People who have a history of myocarditis or pericarditis unrelated to vaccination with Moderna, Novavax, or Pfizer-BioNTech (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 as no evidence of ongoing heart inflammation or sequelae as determined by the person's clinical team. For people who have a history of myocarditis associated with MIS-C or MIS-A, see COVID-19 vaccination and MIS-C and MIS-A.

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.

Safety considerations for Janssen COVID-19 Vaccine

Post-vaccination symptoms

In clinical trials of 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 Janssen COVID-19 Vaccine have been reported in males and females, with the highest risk in females ages 30–49 years.

COVID-19 vaccine recipients should be informed that Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines are recommended over Janssen COVID-19 Vaccine. Due to the risk of TTS, Janssen COVID-19 Vaccine should only be used in limited situations :

- When there is a contraindication to mRNA (i.e., Moderna, Pfizer-BioNTech) and Novavax COVID-19 vaccines (e.g., severe allergic reaction after a previous dose or to a component of an mRNA COVID-19 vaccine) (see Table 4)
- When a person would otherwise remain unvaccinated for COVID-19 due to limited access to other COVID-19 vaccines
- When a person wants to receive 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 (i.e., Moderna and Pfizer-BioNTech) and Novavax COVID-19 vaccines instead of 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 dose at least 2 months following their dose of 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 (i.e., Moderna or Pfizer-BioNTech) or Novavax 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 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 (i.e., booster) 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 as vaccination would not be expected 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) and to 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.

Special situation: administration of tixagevimab/cilgavimab (EVUSHELD™) for pre-exposure prophylaxis should be deferred for at least two weeks after receipt of a dose of COVID-19 vaccine, 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 two criteria:

1. Clinical recovery has been achieved, including return to normal cardiac function; and
2. It has been at least 90 days after the diagnosis of MIS-C

COVID-19 vaccination may also be considered for children and adolescents who had MIS-C and **do not meet both 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 two criteria listed below:

1. Clinical recovery has been achieved, including return to normal cardiac function; and
2. It has been at least 90 days after the diagnosis of MIS-C

For children and adolescents who had MIS-C but do not meet both 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 two 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 (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 (Table 2).

People with autoimmune conditions

People with autoimmune conditions may receive any age-appropriate FDA-approved or FDA-authorized COVID-19 vaccine. As with the general population, mRNA (i.e, Moderna or Pfizer-BioNTech) and Novavax vaccines are recommended; 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, mRNA (i.e., Moderna or Pfizer-BioNTech) and Novavax COVID-19 vaccines are recommended 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; however the affected tests are currently unavailable. 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. 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.
2. 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.
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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