Centers for Disease Control and Prevention

Vaccines & Immunizations

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

Summary of recent changes (last updated September 2, 2022):

- New booster recommendation for people ages 12 years and older to receive 1 bivalent mRNA booster after completion of a monovalent primary series; it replaces all prior booster recommendations for this age group
  - Recommendations for use of a bivalent Moderna booster dose in people ages 18 years and older
  - Recommendations for use of a bivalent Pfizer-BioNTech booster dose in people ages 12 years and older
- Updated guidance for observation periods following COVID-19 vaccination
- Updated guidance on COVID-19 vaccination and multisystem inflammatory syndrome (MIS) in children (MIS-C) and in adults (MIS-A)

Reference Materials

- Summary Document for Interim Clinical Considerations (Updated 8/22/2022)
- Interim COVID-19 Immunization Schedule (Updated 8/22/2022)
- At-A-Glance COVID-19 Vaccination Schedule (Updated 9/6/2022)
- 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 is recommended to receive a COVID-19 primary series vaccination for the prevention of COVID-19; monovalent mRNA COVID-19 vaccines (i.e., Moderna and Pfizer-BioNTech) and Novavax COVID-19 Vaccine are recommended.
- Everyone ages 12 years and older is recommended to receive 1 age-appropriate bivalent mRNA booster dose regardless of primary series product and number of monovalent booster doses previously received.
- Children ages 5-11 years are recommended to receive 1 monovalent mRNA booster dose if eligible (i.e., if a booster dose is FDA-authorized for use in a specified population).
- 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 severe 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

The following 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):

- mRNA vaccines
  - Moderna COVID-19 Vaccine/SPIKEVAX *(1)* and Moderna COVID-19 Vaccine, Bivalent
  - Pfizer-BioNTech COVID-19 Vaccine/COMIRNATY *(2)* and Pfizer-BioNTech COVID-19 Vaccine, Bivalent
- Protein subunit vaccine
  - Novavax COVID-19 Vaccine, Adjuvanted
- Adenovirus vector vaccine
  - Janssen (Johnson & Johnson) COVID-19 Vaccine

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

For primary series vaccination, three monovalent COVID-19 vaccines (listed in alphabetical order by manufacturer), are recommended: Moderna, Novavax, and Pfizer-BioNTech. Bivalent mRNA vaccines are not authorized or approved at this time for primary series doses.

For booster vaccination, Moderna and Pfizer-BioNTech are recommended. A person's eligibility for booster vaccination and the appropriate mRNA booster dose product to use (i.e., monovalent or bivalent) depends on age and primary series product.

Janssen COVID-19 Vaccine is authorized for adults ages 18 years and older in certain limited situations due to safety considerations (see Appendix A).

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. People can stay up to date with COVID-19 vaccination by completing a primary series and receiving the most recent booster dose recommended for them by CDC (see Table 2 and Table 3).

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 is defined in Box 2.

See Appendices B (People who received COVID-19 vaccine outside the United States) and C (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 composition	Vaccine vial cap color	Label border color	Dilution required	Primary series		Booster dose	
					Dose	Injection volume	Dose	Injection volume
6 months–5 years	Monovalent	Dark blue	Magenta	No	25 µg	0.25 mL	NA	NA
6–11 years†	Monovalent	Dark blue	Purple	No	50 µg	0.5 mL	NA	NA
12–17 years	Monovalent	Red	Light blue	No	100 µg	0.5 mL	NA	NA
18 years and older	Monovalent	Red	Light blue	No	100 µg	0.5 mL	NA	NA
18 years and older	Bivalent	Dark blue	Gray	No	NA	NA	50 µg	0.5 mL

Novavax

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

Janssen

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

Abbreviations: 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.

†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. It is not authorized for the booster dose.

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

Box 2. Terminology for COVID-19 vaccine use

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

Additional dose: A dose of vaccine administered after the primary series to people who 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 are recommended to receive an additional dose using an mRNA vaccine.

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 manufacturer used for the booster dose and the primary series.
- **Heterologous booster dose (mix-and-match booster):** A different vaccine manufacturer used for the booster dose and the primary series.

Monovalent vaccine: The vaccine product is based on the original (ancestral) strain of SARS-CoV-2.

Bivalent vaccine ("updated vaccine"): The vaccine product is based on the original (ancestral) strain of SARS-CoV-2 and the Omicron BA.4 and BA.5 (BA.4/BA.5) variants of SARS-CoV-2.

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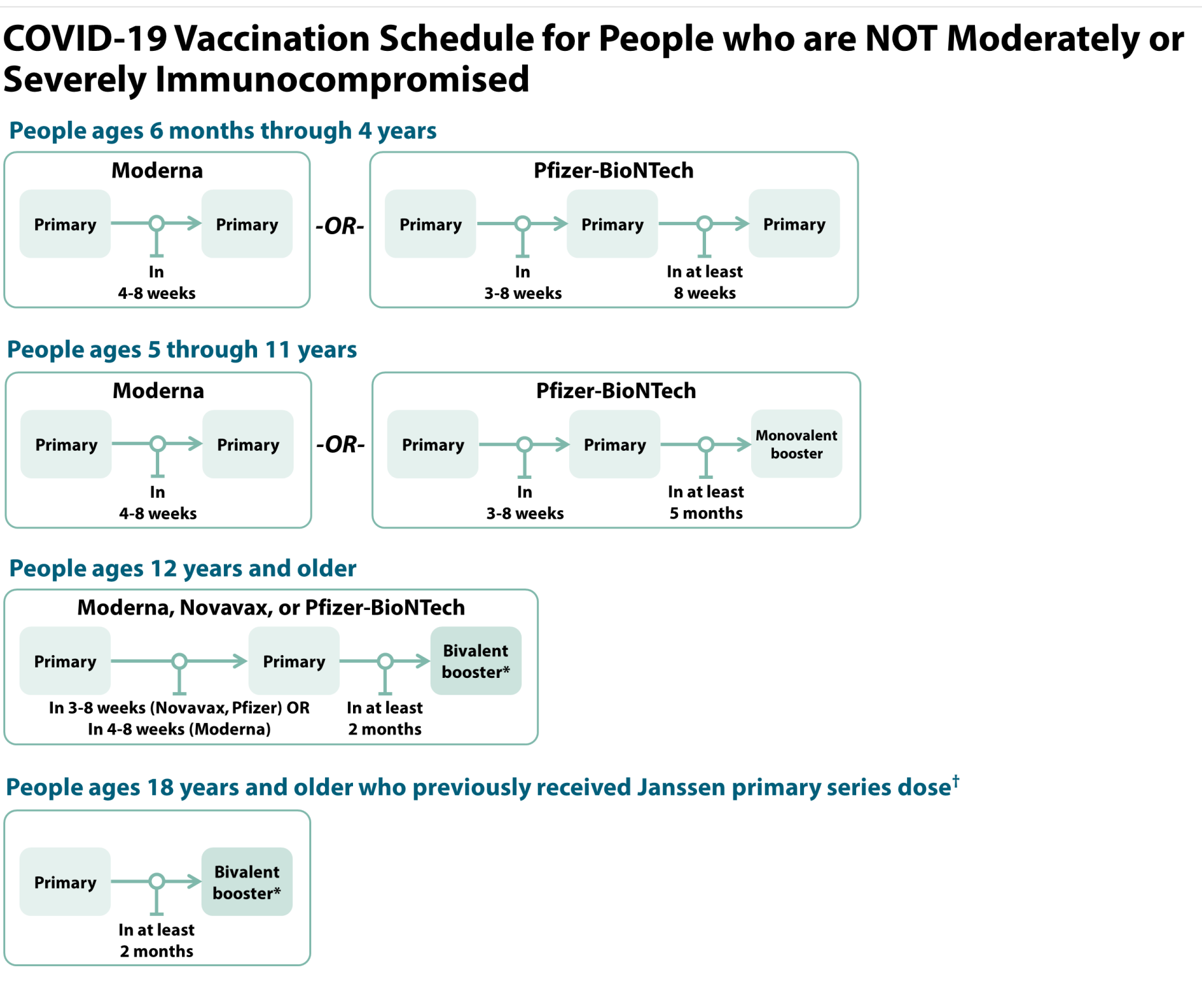
COVID-19 vaccination guidance for people who are **not** moderately or severely immunocompromised

Overview

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



*The bivalent booster dose is administered at least 2 months after completion of the primary series. For people who previously received a monovalent booster dose(s), the bivalent booster dose is administered at least 2 months after the last monovalent booster dose.
†Janssen COVID-19 Vaccine should only be used in certain limited situations. See: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-a

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; only monovalent vaccines are approved or authorized for primary series doses. The same vaccine product should be used for all doses of the primary series (see Interchangeability of COVID-19 vaccine products).

For booster vaccination, Moderna and Pfizer-BioNTech are recommended. Recommendations vary based on age and primary series product. **People ages 12 years and older are recommended to receive 1 age-appropriate bivalent mRNA booster dose after completion of any FDA-approved or FDA-authorized monovalent primary series or previously received monovalent booster dose(s). This new booster recommendation replaces all prior booster recommendations for this age group.** Monovalent mRNA vaccines are no longer authorized as a booster dose for people ages 12 years and older.

Children ages 5–11 years are recommended to receive 1 monovalent mRNA booster dose if eligible (i.e., if a booster dose is FDA-authorized for use in a specified population).

For information on the timing of COVID-19 vaccination (primary series and booster doses) after SARS-CoV-2 infection, see COVID-19 vaccination and SARS-CoV-2 infection.

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

Ages 6 months through 11 years

Primary series manufacturer	Age group	Number of primary doses	Number of monovalent booster doses	Recommended monovalent booster dose	Interval between 1st and 2nd primary dose*	Interval between 2nd and 3rd primary dose	Interval between primary series and booster dose
Moderna	6 months–5 years	2	NA	NA	4–8 weeks	NA	NA
Moderna	6–11 years	2	NA	NA	4–8 weeks	NA	NA
Pfizer-BioNTech	6 months–4 years	3	NA	NA	3–8 weeks	At least 8 weeks	NA
Pfizer-BioNTech	5–11 years	2	1	Pfizer-BioNTech	3–8 weeks	NA	At least 5 months

Ages 12 through 17 years

Primary series manufacturer	Age group	Number of primary doses	Number of bivalent booster doses	Recommended bivalent booster dose†	Interval between 1st and 2nd primary dose*	Interval between primary series and booster dose‡
Moderna	12–17 years	2	1	Pfizer-BioNTech	4–8 weeks	At least 2 months
Novavax	12–17 years	2	1	Pfizer-BioNTech	3–8 weeks	At least 2 months
Pfizer-BioNTech	12–17 years	2	1	Pfizer-BioNTech	3–8 weeks	At least 2 months

Ages 18 years and older

Primary series manufacturer	Age group	Number of primary doses	Number of bivalent booster doses	Recommended bivalent booster dose†	Interval between 1st and 2nd primary dose*	Interval between primary series and booster dose‡
Moderna	18 years and older	2	1	Moderna or Pfizer-BioNTech	4–8 weeks	At least 2 months
Novavax	18 years and older	2	1	Moderna or Pfizer-BioNTech	3–8 weeks	At least 2 months
Pfizer-BioNTech	18 years and older	2	1	Moderna or Pfizer-BioNTech	3–8 weeks	At least 2 months

Abbreviation: NA = not authorized

*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 and 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.
†For people ages 12 years and older, 1 bivalent mRNA booster dose is recommended after completion of any FDA-approved or FDA-authorized monovalent primary series or previously received monovalent booster dose(s). The bivalent Moderna booster dose is authorized for people ages 18 years and older; the bivalent Pfizer-BioNTech booster dose is authorized for people ages 12 years and older.

‡The bivalent booster dose is administered at least 2 months after completion of the primary series. For people who previously received a monovalent booster dose(s), the bivalent booster dose is administered at least 2 months after the last monovalent booster dose.

Schedule: ages 6 months through 11 years

Moderna COVID-19 Vaccine

- Children ages 6 months–5 years: A 2-dose primary series separated by 4–8 weeks is recommended. 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: A 2-dose primary series separated by 4–8 weeks is recommended. 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: A 3-dose primary series is recommended. 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: A 2-dose primary series and 1 booster dose is recommended. The primary series doses are separated by 3-8 weeks and the booster dose is administered at least 5 months after completion of the primary series. Currently, the monovalent Pfizer-BioNTech booster dose is authorized for children in this age group who receive a Pfizer-BioNTech primary series.

Schedule: ages 12 through 17 years

Moderna COVID-19 Vaccine

- Adolescents ages 12–17 years: A 2-dose primary series and 1 age-appropriate bivalent mRNA booster dose is recommended. The primary series doses are separated by 4-8 weeks and the bivalent mRNA booster dose is administered at least 2 months after completion of the primary series (for people who have not received any booster doses), or at least 2 months after the last monovalent booster dose. Currently, the bivalent Pfizer-BioNTech booster dose is authorized for adolescents in this age group who receive a Moderna primary series.

Novavax COVID-19 Vaccine

- Adolescents ages 12–17 years: A 2-dose primary series and 1 age-appropriate bivalent mRNA booster dose is recommended. The primary series doses are separated by 3-8 weeks and the bivalent mRNA booster dose is administered at least 2 months after completion of the primary series. Currently, the bivalent Pfizer-BioNTech booster dose is authorized for adolescents in this age group who receive a Novavax primary series.

Pfizer-BioNTech COVID-19 Vaccine

- Adolescents ages 12–17 years: A 2-dose primary series and 1 age-appropriate bivalent mRNA booster dose is recommended. The primary series doses are separated by 3-8 weeks and the bivalent mRNA booster dose is administered at least 2 months after completion of the primary series (for people who have not received any booster doses), or at least 2 months after the last monovalent booster dose. Currently, the bivalent Pfizer-BioNTech booster dose is authorized for adolescents in this age group who receive a Pfizer-BioNTech primary series.

Schedule: ages 18 years and older

Moderna COVID-19 Vaccine

- Adults ages 18 years and older: A 2-dose primary series and 1 bivalent mRNA booster dose (Moderna or Pfizer-BioNTech) is recommended. The primary series doses are separated by 4–8 weeks and the bivalent mRNA booster dose is administered at least 2 months after completion of the primary series (for people who have not received any booster doses), or at least 2 months after the last monovalent booster dose.

Novavax COVID-19 Vaccine

- Adults ages 18 years and older: A 2-dose primary series and 1 bivalent mRNA booster dose (Moderna or Pfizer-BioNTech) is recommended. The primary series doses are separated by 3–8 weeks and the bivalent mRNA booster dose is administered at least 2 months after completion of the primary series.

Pfizer-BioNTech COVID-19 Vaccine

- Adults ages 18 years and older: A 2-dose primary series and 1 bivalent mRNA booster dose (Moderna or Pfizer-BioNTech) is recommended. The primary series doses are separated by 3–8 weeks and the bivalent mRNA booster dose is administered at least 2 months after completion of the primary series (for people who have not received any booster doses), or at least 2 months after the last monovalent booster dose.

Previous vaccination with Janssen COVID-19 Vaccine

People ages 18 years and older who received the Janssen COVID-19 Vaccine primary series dose are recommended to receive 1 bivalent mRNA booster dose (Moderna or Pfizer-BioNTech) at least 2 months after completion of the primary series dose (for people who have not received any booster doses), or at least 2 months after the last monovalent booster dose.

See Appendix A for additional information on Janssen COVID-19 Vaccine.

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 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 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 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 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.

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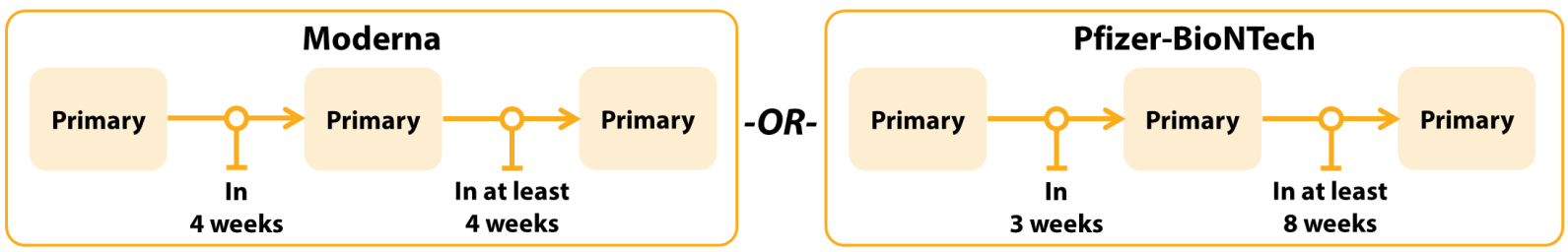
COVID-19 vaccination guidance for people who are moderately or severely immunocompromised

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; see also COVID-19 vaccination and EVUSHELD™.

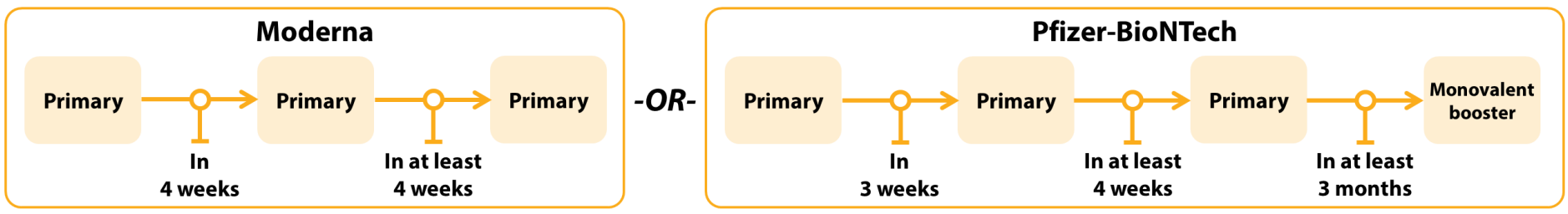
Overview

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

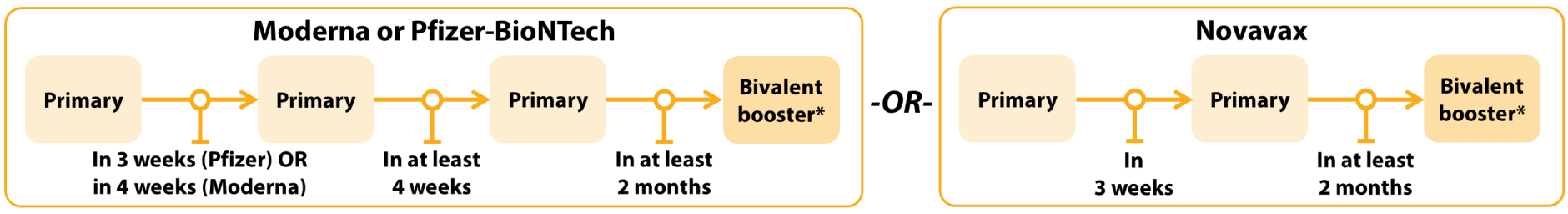
People ages 6 months through 4 years



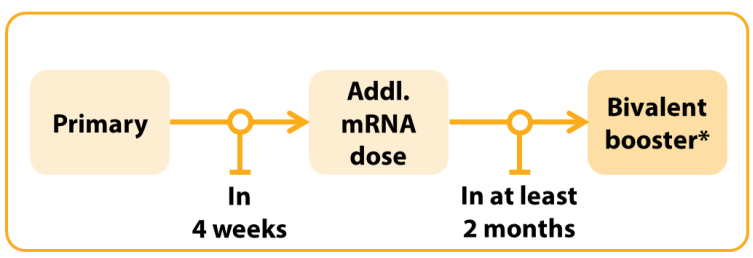
People ages 5 through 11 years



People ages 12 years and older

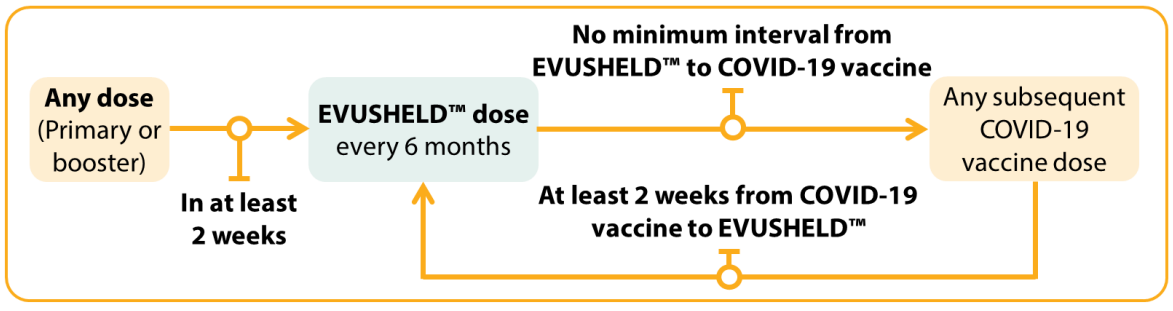


People ages 18 years and older who previously received Janssen primary series dose†



Monoclonal antibodies (EVUSHELD™) for COVID-19 pre-exposure prophylaxis

People ages 12 years and older (must weigh at least 40kg)



*The bivalent booster dose is administered at least 2 months after completion of the primary series. For people who previously received a monovalent booster dose(s), the bivalent booster dose is administered at least 2 months after the last monovalent booster dose.

†Janssen COVID-19 Vaccine should only be used in certain limited situations. See: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-a

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; only monovalent vaccines are approved or authorized for primary series doses. The same vaccine product should be used for all doses of the primary series (see Interchangeability of COVID-19 vaccine products)

doses of the primary series (see Interchangeability of COVID-19 vaccine products).

For booster vaccination, Moderna and Pfizer-BioNTech are recommended. Recommendations vary based on age and primary series product. **People ages 12 years and older are recommended to receive 1 age-appropriate bivalent mRNA booster dose after completion of any FDA-approved or FDA-authorized monovalent primary series or previously received monovalent booster dose(s). This new booster recommendation replaces all prior booster recommendations for this age group.** Monovalent mRNA vaccines are no longer authorized as a booster dose for people ages 12 years and older.

Children ages 5–11 years are recommended to receive 1 monovalent mRNA booster dose if eligible (i.e., if a booster dose is FDA-authorized for use in a specified population).

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 primary series do not need additional primary doses; however, they should follow the schedule for people who are moderately or severely immunocompromised for the booster dose. 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.

For information on the timing of COVID-19 vaccination (primary series and booster doses) after SARS-CoV-2 infection, see COVID-19 vaccination and SARS-CoV-2 infection.

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

Ages 6 months through 11 years

Primary series manufacturer	Age group	Number of primary doses	Number of monovalent booster doses	Recommended monovalent booster dose	Interval between 1st and 2nd primary dose	Interval between 2nd and 3rd primary dose	Interval between primary series and booster dose
Moderna	6 months–5 years	3	NA	NA	4 weeks	At least 4 weeks	NA
Moderna	6–11 years	3	NA	NA	4 weeks	At least 4 weeks	NA
Pfizer-BioNTech	6 months–4 years	3	NA	NA	3 weeks	At least 8 weeks	NA
Pfizer-BioNTech	5–11 years	3	1	Pfizer-BioNTech	3 weeks	At least 4 weeks	At least 3 months

Ages 12 through 17 years

Primary series manufacturer	Age group	Number of primary doses	Number of bivalent booster doses	Recommended bivalent booster dose*	Interval between 1st and 2nd primary dose	Interval between 2nd and 3rd primary dose	Interval between primary series and booster dose†
Moderna	12–17 years	3	1	Pfizer-BioNTech	4 weeks	At least 4 weeks	At least 2 months
Novavax	12–17 years	2	1	Pfizer-BioNTech	3 weeks	NA	At least 2 months
Pfizer-BioNTech	12–17 years	3	1	Pfizer-BioNTech	3 weeks	At least 4 weeks	At least 2 months

Ages 18 years and older

Primary series manufacturer	Age group	Number of primary doses	Number of bivalent booster doses	Recommended bivalent booster dose*	Interval between 1st and 2nd primary dose	Interval between 2nd and 3rd primary dose	Interval between primary series and booster dose†
Moderna	18 years and older	3	1	Moderna or Pfizer-BioNTech	4 weeks	At least 4 weeks	At least 2 months

Primary series manufacturer	Age group	Number of primary doses	Number of bivalent booster doses	Recommended bivalent booster dose*	Interval between 1st and 2nd primary dose	Interval between 2nd and 3rd primary dose	Interval between primary series and booster dose†
Novavax	18 years and older	2	1	Moderna or Pfizer-BioNTech	3 weeks	NA	At least 2 months
Pfizer-BioNTech	18 years and older	3	1	Moderna or Pfizer-BioNTech	3 weeks	At least 4 weeks	At least 2 months

Abbreviation: NA = not authorized

*For people ages 12 years and older, 1 bivalent mRNA booster dose is recommended after completion of any FDA-approved or FDA-authorized monovalent primary series or previously received monovalent booster dose(s). The bivalent Moderna booster dose is authorized for people ages 18 years and older; the bivalent Pfizer-BioNTech booster dose is authorized for people ages 12 years and older.

†The bivalent booster dose is administered at least 2 months after completion of the primary series. For people who previously received a monovalent booster dose(s), the bivalent booster dose is administered at least 2 months after the last monovalent booster dose.

Schedule: ages 6 months through 11 years

Moderna COVID-19 Vaccine

- Children ages 6 months–5 years: A 3-dose primary series is recommended. 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: A 3-dose primary series is recommended. 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: A 3-dose primary series is recommended. 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: A 3-dose primary series and 1 booster dose is recommended. 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. Currently, the monovalent Pfizer-BioNTech booster dose is authorized for children in this age group who receive a Pfizer-BioNTech primary series.

Schedule: ages 12 through 17 years

Moderna COVID-19 Vaccine

- Adolescents ages 12–17 years: A 3-dose primary series and 1 age-appropriate bivalent mRNA booster dose is recommended. 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 bivalent mRNA booster dose is administered at least 2 months after completion of the primary series (for people who have not received any booster doses), or at least 2 months after the last monovalent booster dose. Currently, the bivalent Pfizer-BioNTech booster dose is authorized for adolescents in this age group who receive a Moderna primary series.

Novavax COVID-19 Vaccine

- Adolescents ages 12–17 years: A 2-dose primary series and 1 age-appropriate bivalent mRNA booster dose is recommended. For the primary series, the first and second doses are separated by 3 weeks. The bivalent mRNA booster dose is administered at least 2 months after completion of the primary series. Currently, the bivalent Pfizer-BioNTech booster dose is authorized for adolescents in this age group who receive a Novavax primary series.

Pfizer-BioNTech COVID-19 Vaccine

Pfizer-BioNTech COVID-19 Vaccine

- Adolescents ages 12–17 years: A 3-dose primary series and 1 age-appropriate bivalent mRNA booster dose is recommended. 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 bivalent mRNA booster dose is administered at least 2 months after completion of the primary series (for people who have not received any booster doses), or at least 2 months after the last monovalent booster dose. Currently, the bivalent Pfizer-BioNTech booster dose is authorized for adolescents in this age group who receive a Pfizer-BioNTech primary series.

Schedule: ages 18 years and older

Moderna COVID-19 Vaccine

- Adults ages 18 years and older: A 3-dose primary series and 1 bivalent mRNA booster dose (Moderna or Pfizer-BioNTech) is recommended. 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 bivalent mRNA booster dose is administered at least 2 months after completion of the primary series (for people who have not received any booster doses), or at least 2 months after the last monovalent booster dose.

Novavax COVID-19 Vaccine

- Adults ages 18 years and older: A 2-dose primary series and 1 bivalent mRNA booster dose (Moderna or Pfizer-BioNTech) is recommended. The primary series doses are separated by 3 weeks and the bivalent mRNA booster dose is administered at least 2 months after completion of the primary series.

Pfizer-BioNTech COVID-19 Vaccine

- Adults ages 18 years and older: A 3-dose primary series and 1 bivalent mRNA booster dose (Moderna or Pfizer-BioNTech) is recommended. 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 bivalent mRNA booster dose is administered at least 2 months after completion of the primary series (for people who have not received any booster doses), or at least 2 months after the last monovalent booster dose.

Previous vaccination with Janssen COVID-19 Vaccine

People who are moderately or severely immunocompromised ages 18 years and older who received the Janssen COVID-19 Vaccine primary series dose are recommended to receive a second (additional) dose using a monovalent mRNA vaccine and 1 bivalent mRNA booster dose (Moderna or Pfizer-BioNTech). The primary series dose and the additional dose are separated by at least 4 weeks. The bivalent mRNA booster dose is administered at least 2 months after the additional dose (for people who have not received any booster doses), or at least 2 months after the last monovalent booster dose.

See Appendix A for additional information on Janssen COVID-19 Vaccine.

COVID-19 vaccination and EVUSHELD™

In addition to following the recommended COVID-19 vaccination schedule, tixagevimab/cilgavimab (EVUSHELD™), a combination of two monoclonal antibodies, should be administered to people who are moderately or severely immunocompromised every 6 months for pre-exposure prophylaxis to supplement vaccine protection. Per the product EUA , EVUSHELD™ is given at least 2 weeks after COVID-19 vaccine. People may initiate EVUSHELD™ at any time after this interval, including between doses in the primary series and primary and booster doses. Providers should consult CDC's EVUSHELD™ guidance and current treatment guidelines for more information on the use of EVUSHELD™ as pre-exposure prophylaxis. Such use of monoclonal antibodies, however, is not a substitute for COVID-19 vaccination.

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 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) or untreated HIV infection
- 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 should undergo revaccination for the monovalent primary series and bivalent booster doses received prior to or during treatment. There is no revaccination for monovalent booster doses. Revaccination cannot exceed the number of primary series and booster doses currently authorized (see Table 3). 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 (primary series and bivalent booster doses) 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). There is no revaccination for monovalent booster doses. Revaccination cannot exceed the number of primary series and booster doses currently authorized. 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, and appropriate timing of revaccination.

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

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 D. Doses administered at any time after the recommended interval are valid.

Interchangeability of COVID-19 vaccine products

Primary series

In general, the same monovalent 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 received 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 homologous or heterologous age-appropriate mRNA vaccine can be used if a booster dose is FDA-authorized for use in a specified population.

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. Studies that compared coadministration of COVID-19 vaccines and seasonal influenza vaccines with separate administration of these vaccines found similar levels of immunogenicity and similar or slightly higher reactogenicity; no specific safety concerns were identified.

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.

Orthopoxvirus vaccination:

- If an orthopoxvirus vaccine is recommended for prophylaxis in the setting of an orthopoxvirus (e.g., monkeypox) 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.
- 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 because of the observed risk for myocarditis and pericarditis 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 and pericarditis after JYNNEOS.

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 the booster dose, 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 series and booster doses) 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.

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 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.

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.

Post-vaccination observation period

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. Patients should be seated or lying down during vaccination. Vaccination providers, particularly when vaccinating adolescents, should consider observing vaccine recipients for 15 minutes after vaccination. If syncope develops, patients should be observed until symptoms resolve.

Additionally, providers should consider observing people with the following medical histories for 30 minutes after COVID-19 vaccination to monitor for allergic reactions:

- Allergy-related contraindication to a different type of COVID-19 vaccine
- Non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine.
- Anaphylaxis after non-COVID-19 vaccines or injectable therapies

See also Contraindications and precautions.

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 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. 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.
History of anaphylaxis after any vaccine other than COVID-19 vaccine or after 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 have a precaution to the **same type of COVID-19 vaccine.**	Precaution	

Medical condition or history	Guidance	Recommended action(s)
People with an allergy-related contraindication to one type of COVID-19 vaccine have a precaution to the **other types of COVID-19 vaccines.** **Special situation**: People with a known allergy to polysorbate have a contraindication to both Novavax and Janssen 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: MIS-C = multisystem inflammatory syndrome in children; MIS-A = multisystem inflammatory syndrome in adults

For information on contraindications and precautions to Janssen COVID-19 vaccination, see Appendix A.

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
- Management of anaphylaxis after COVID-19 vaccination

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 anaphylaxis after other vaccines or injectable therapies (Appendix E, footnote 3). 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 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.

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 and the provider agreement for the CDC COVID-19 Vaccination Program 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 myocarditis after a Pfizer-BioNTech or a Moderna vaccine
- Cases of pericarditis after a Pfizer-BioNTech or a Moderna vaccine
- 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.

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, including adolescents; redness and swelling were reported less frequently. Fatigue/malaise, 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 12–64 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 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 and pericarditis have occurred most frequently, although not exclusively, in adolescent and young adult males within the first week after receiving the second dose or a booster dose of an mRNA COVID-19 vaccine. The reporting rates for myocarditis after mRNA COVID-19 primary series vaccination or booster vaccination exceed the background rates in several age groups in males and females with the highest rates observed in males ages 12–39 years; see the June 23, 2022 and September 1, 2022 ACIP meetings for more information.

Based on the overall data to date, the risk for myocarditis and pericarditis after an mRNA COVID-19 booster dose in adolescents and young adults appears generally similar to or lower than the risk after a second mRNA COVID-19 vaccine primary series dose.

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 post-authorization 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. To date, post-authorization surveillance has not detected an increased risk for myocarditis and pericarditis following mRNA COVID-19 vaccination in children ages 6 months–4 years (Pfizer-BioNTech) and ages 6 months–5 years (Moderna).

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 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 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 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 information on potential use of Janssen COVID-19 Vaccine, see Appendix A.

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

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.

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COVID-19 vaccination and SARS-CoV-2 infection

People exposed to SARS-CoV-2

Recent exposure to SARS-CoV-2 is not a contraindication or precaution to COVID-19 vaccination. People with a known or potential SARS-CoV-2 exposure can receive vaccine if they do not have symptoms consistent with SARS-CoV-2 infection; however, people should follow CDC's post-exposure guidance.

COVID-19 vaccines are not recommended for post-exposure prophylaxis. People should be informed that vaccination is to help prevent severe COVID-19 following future exposures. 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 vaccine 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 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. See COVID-19 vaccination and EVUSHELD™ for more information on the timing of EVUSHELD™ administration.

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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 (MIS C/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

People with a history of MIS-C or MIS-A

Experts consider the benefits of COVID-19 vaccination for people with a history of MIS-C/A (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 baseline cardiac function; and
2. It has been at least 90 days after the diagnosis of MIS-C/A

COVID-19 vaccination may also be considered for people who had MIS-C/A 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 baseline cardiac function, as an important factor when considering COVID-19 vaccination. Additional factors, such as the 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/A should take into consideration current or planned immunomodulatory therapies for treatment of MIS-C/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, in addition to other potential etiologies as clinically indicated. 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 vaccine dose

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 baseline cardiac function; and
2. It has been at least 90 days after the diagnosis of MIS-C/A

For people who had MIS-C/A but do not meet both criteria above, 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 vaccine dose

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/A was a complication of a recent SARS-CoV-2 infection.

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. No increased risk of GBS has been identified with receipt of mRNA COVID-19 vaccines.

See Appendix A for information on GBS and 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 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 (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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