Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States

Summary of recent changes (last updated October 6, 2023):

- The updated 2023–2024 formulation of Novavax COVID-19 Vaccine is recommended for people ages 12 years and older as follows:
  - Initial vaccination: 2 doses of updated (2023–2024 Formula) Novavax COVID-19 Vaccine
  - Previously vaccinated with any Original monovalent or bivalent COVID-19 vaccine (Moderna, Novavax, Pfizer-BioNTech, Janssen): 1 dose of updated (2023–2024 Formula) Novavax Vaccine
- People who are moderately or severely immunocompromised may receive 1 or more additional updated (2023–2024 Formula) Novavax vaccine doses.
- People ages 12 years and older have the option of receiving either the updated (2023–2024 Formula) mRNA (Moderna, Pfizer-BioNTech) or updated (2023–2024 Formula) Novavax vaccine.

Overview of COVID-19 vaccination

These clinical considerations provide information to healthcare professionals and public health officials on use of COVID-19 vaccines. They are informed by:

- Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC)
- COVID-19 vaccine approval (licensure) under a Biologics License Application (BLA) or authorization under an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA)
- CDC's Emergency Use Instructions (EUI) for FDA-approved vaccines
- Emergency Use Listing (EUL) of COVID-19 vaccines by the World Health Organization (WHO)
- ACIP's General Best Practice Guidelines for Immunization
- Expert opinion

COVID-19 vaccines

Two types of COVID-19 vaccines are available for use in the United States:

- mRNA vaccines
  - Moderna COVID-19 Vaccine (2023–2024 Formula) is authorized for children ages 6 months–11 years; SPIKEVAX is the licensed Moderna product for people ages 12 years and older. These vaccines are hereafter referred to as updated (2023–2024 Formula) Moderna COVID-19 Vaccine.
  - Pfizer-BioNTech COVID-19 Vaccine (2023–2024 Formula) is authorized for children ages 6 months–11 years; COMIRNATY is the licensed Pfizer-BioNTech product for people ages 12 years and older. These vaccines are hereafter referred to as updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vaccine.
- Protein subunit vaccine
  - Novavax COVID-19 Vaccine, Adjuvanted (hereafter referred to as Novavax COVID-19 Vaccine) is authorized for people ages 12 years and older.

COVID-19 vaccine composition

- The 2023–2024 formulation for all COVID-19 vaccines licensed or authorized in the United States (Moderna, Novavax, and Pfizer-BioNTech) has been updated to a monovalent vaccine based on the Omicron XBB.1.5 sublineage of SARS-CoV-2. The Original monovalent and bivalent (Original and Omicron BA.4/BA.5) formulations should no longer be used.

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

Recommendations for the use of COVID-19 vaccines

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. There is currently no FDA-approved or FDA-authorized COVID-19 vaccine for children younger than age 6 months. CDC recommends that people stay up to date with COVID-19 vaccination.

There is no preferential recommendation for the use of any one COVID-19 vaccine over another when more than one recommended and age-appropriate vaccine is available.

Vaccination schedules can be found in Table 1 for people who are not moderately or severely immunocompromised and in Table 2 for people who are moderately or severely immunocompromised. See Appendix A for recommendations for people who received COVID-19 vaccine outside the United States.

Vaccine dosage and administration

In general, CDC recommends that people receive the age-appropriate vaccine product and dosage based on their age on the day of vaccination and in accordance with the recommended intervals for that age group *(1)*. However, for COVID-19 vaccination there is an exception for children who receive the Pfizer-BioNTech COVID-19 Vaccine and transition from age 4 years to 5 years during the 3-dose vaccination series (see Transitioning from a younger to older age group).

Vaccine doses should be administered by the intramuscular route.

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

The COVID-19 vaccination schedule for people who are not moderately or severely immunocompromised is detailed in Table 1. The recommended vaccine type and number of updated (2023–2024 Formula) COVID-19 vaccine doses are based on age and vaccination history.

Ages 6 months–4 years

- Unvaccinated: 2 or 3 **homologous** (i.e., from the same manufacturer) updated (2023–2024 Formula) mRNA vaccine doses, depending on vaccine manufacturer (i.e., Moderna, Pfizer-BioNTech).
- Previously received an incomplete series of Original monovalent or bivalent mRNA vaccine doses: Complete the vaccination series with 1 or 2 **homologous** updated (2023–2024 Formula) mRNA vaccine doses, depending on vaccine manufacturer and the number of previous vaccine doses.
- Previously received all doses in the initial vaccination series with Original monovalent or bivalent mRNA vaccine: 1 **homologous** updated (2023–2024 Formula) mRNA vaccine dose.

Ages 5–11 years

- Unvaccinated or previously received any number of Original monovalent or bivalent mRNA vaccine doses: 1 dose of an updated (2023–2024 Formula) mRNA vaccine from either manufacturer (i.e., Moderna or Pfizer-BioNTech).

Ages 12 years and older

- Unvaccinated: 1 dose of an updated (2023–2024 Formula) mRNA COVID-19 vaccine (i.e., Moderna, Pfizer-BioNTech) **OR** 2 doses of updated (2023–2024 Formula) Novavax vaccine.
- Previously received 1 or more Original monovalent or bivalent mRNA vaccine doses: 1 dose of any updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
- Previously received 1 or more doses of Original monovalent Novavax vaccine, alone or in combination with any Original monovalent or bivalent mRNA vaccine doses: 1 dose of any updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
- Previously received 1 or more doses of Janssen vaccine, alone or in combination with any Original monovalent or bivalent mRNA vaccine or Original monovalent Novavax doses: 1 dose of any updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).

Table 1. People who are not moderately or severely immunocompromised: Recommended COVID-19 vaccination schedule by COVID-19 vaccination history, October 6, 2023

Updated (2023–2024 Formula) COVID-19 vaccines

Ages 6 months–4 years

COVID-19 vaccination history prior to updated (2023–2024 Formula) vaccine*	Updated (2023–2024 Formula) vaccine	Number of updated (2023–2024 Formula) vaccine doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
Unvaccinated	Moderna	2	0.25 mL/25 ug	Dark blue cap; green label	Dose 1 and Dose 2: 4–8 weeks†
	OR				
	Pfizer-BioNTech	3	0.3 mL/3 ug	Yellow cap; yellow label	Dose 1 and Dose 2: 3–8 weeks† Dose 2 and Dose 3: At least 8 weeks
1 dose any Moderna	Moderna	1	0.25 mL/25 ug	Dark blue cap; green label	4–8 weeks after last dose†
2 or more doses any Moderna	Moderna	1	0.25 mL/25 ug	Dark blue cap; green label	At least 8 weeks after last dose
1 dose any Pfizer-BioNTech	Pfizer-BioNTech	2	0.3 mL/3 ug	Yellow cap; yellow label	Dose 1: 3–8 weeks after last dose† Dose 1 and Dose 2: At least 8 weeks
2 doses any Pfizer-BioNTech	Pfizer-BioNTech	1	0.3 mL/3 ug	Yellow cap; yellow label	At least 8 weeks after last dose
3 or more doses any Pfizer-BioNTech	Pfizer-BioNTech	1	0.3 mL/3 ug	Yellow cap; yellow label	At least 8 weeks after last dose

Ages 5–11 years‡

COVID-19 vaccination history prior to updated (2023–2024 Formula) vaccine*	Updated (2023–2024 Formula) vaccine	Number of updated (2023–2024 Formula) doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
Unvaccinated	Moderna	1	0.25 mL/25 ug	Dark blue cap; green label	—
	OR				
	Pfizer-BioNTech	1	0.3 mL/10 ug	Blue cap; blue label	—
1 or more doses any mRNA	Moderna	1	0.25 mL/25 ug	Dark blue cap; green label	At least 8 weeks after last dose
	OR				
	Pfizer-BioNTech	1	0.3 mL/10 ug	Blue cap; blue label	At least 8 weeks after last dose

Ages 12 years and older

COVID-19 vaccination history prior to updated (2023–2024 Formula) vaccine*	Updated (2023–2024 Formula) vaccine	Number of updated (2023–2024 Formula) doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors§	Interval between doses
Unvaccinated	Moderna	1	0.5 mL/50 ug	Dark blue cap; blue label	—
	OR				
	Novavax	2	0.5 mL/5 ug rS protein and 50 ug Matrix-M adjuvant	Blue cap; blue label	Dose 1 and Dose 2: 3–8 weeks†
	OR				
	Pfizer-BioNTech	1	0.3 mL/30 ug	Gray cap; gray label	—
1 or more doses any mRNA; 1 or more doses Novavax or Janssen, including in combination with any Original monovalent or bivalent COVID-19 vaccine doses	Moderna	1	0.5 mL/50 ug	Dark blue cap; blue label	At least 8 weeks after last dose
	OR				
	Novavax	1	0.5 mL/5 ug rS protein and 50 ug Matrix-M adjuvant	Blue cap; blue label	At least 8 weeks after last dose
	OR				
	Pfizer-BioNTech	1	0.3 mL/30 ug	Gray cap; gray label	At least 8 weeks after last dose

*COVID-19 vaccination history refers to previous receipt of doses of Original monovalent mRNA or bivalent mRNA vaccine or a combination of the two; for people ages 12 years and older, Original monovalent Novavax COVID-19 Vaccine doses, alone or in combination with any mRNA vaccine doses; and for people ages 18 years and older, Janssen COVID-19 Vaccine doses, alone or in combination with any mRNA or Original monovalent Novavax vaccine doses.

†An 8-week interval between the first and second COVID-19 vaccine (Moderna, Novavax, and Pfizer-BioNTech) doses might be optimal for some people as it might reduce the small risk of myocarditis and pericarditis associated with these vaccines.

‡The FDA EUA provides that children who transition from age 4 years to age 5 years during the Pfizer-BioNTech vaccination series complete the 3-dose series with updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vaccine for ages 6 months–4 years, 0.3 mL/3 ug (yellow cap; yellow label). The FDA EUA provides that children who transition from age 4 years to age 5 years during the Moderna vaccination series complete the 2-dose series; there is no dosage change.

§Updated (2023–2024 Formula) Moderna COVID-19 Vaccine and updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vaccine are also available in a prefilled, single-dose syringe for people ages 12 years and older.

Special situation: For children ages 6 months–4 years who received 1 dose of Moderna and 1 dose of Pfizer-BioNTech, see the section on Interchangeability for guidance on completing the initial vaccination series.

People ages 65 years and older should only receive the recommended number of dose(s) of updated (2023–2024 Formula) mRNA or Novavax vaccine; an additional dose of COVID-19 vaccine is **not** recommended at this time. ACIP will continue to evaluate available data on the epidemiology of COVID-19 and the safety and effectiveness of COVID-19 vaccines. Based on these assessments, ACIP will update COVID-19 vaccine policy and guidance as needed, especially for people at increased risk for severe COVID-19, including people ages 65 years and older.

Considerations for extended intervals for COVID-19 vaccine doses

An 8-week interval between the first and second mRNA COVID-19 vaccine (Moderna, Pfizer-BioNTech) doses and between the first and second doses of Novavax COVID-19 Vaccine might be optimal for some people as it might reduce the small risk of myocarditis and pericarditis associated with these COVID-19 vaccines.

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 for additional information). 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.

Under the current COVID-19 vaccination schedule (Table 1), the extended interval consideration applies only to people who are not moderately or severely immunocompromised and either ages 6 months–4 years, depending on their vaccination history, or ages 12 years–64 years and receiving a 2-dose Novavax series. The minimum interval between the first and second doses continues to be recommended for people who are moderately or severely immunocompromised, people ages 65 years and older receiving Novavax vaccine, and in situations when the fullest possible protection needs to be achieved sooner (e.g., increased concern about an individual's higher risk for severe disease).

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

The COVID-19 vaccination schedule for people who are moderately or severely immunocompromised is detailed in Table 2. The recommended vaccine type and number of updated (2023–2024 Formula) COVID-19 vaccine doses are based on age and vaccination history.

Ages 6 months–4 years

- Unvaccinated: 3 **homologous** (i.e., from the same manufacturer) updated (2023–2024 Formula) mRNA vaccine doses (i.e., Moderna, Pfizer-BioNTech).
- Previously received 1 or 2 Original monovalent or bivalent mRNA vaccine doses: Complete the 3-dose series with 2 or 1 **homologous** updated (2023–2024 Formula) mRNA vaccine doses, respectively.
- Previously received a combined total of 3 or more Original monovalent or bivalent mRNA vaccine doses: 1 dose of **homologous** updated (2023–2024 Formula) mRNA vaccine.
- Additional doses: May receive 1 or more additional **homologous** updated (2023–2024 Formula) mRNA vaccine doses.

Ages 5–11 years

- Unvaccinated: 3 **homologous** (i.e., from the same manufacturer) updated (2023–2024 Formula) mRNA vaccine doses (i.e., Moderna, Pfizer-BioNTech).
- Previously received 1 or 2 Original monovalent or bivalent mRNA vaccine doses: Complete the 3-dose series with 2 or 1 **homologous** updated (2023–2024 Formula) mRNA vaccine doses, respectively.
- Previously received a combined total of 3 or more Original monovalent or bivalent mRNA vaccine doses: 1 dose of updated (2023–2024 Formula) mRNA vaccine from either manufacturer.
- Additional doses: May receive 1 or more additional updated (2023–2024 Formula) mRNA vaccine doses from either manufacturer.

Ages 12 years and older

- Unvaccinated: 3 **homologous** (i.e., from the same manufacturer) updated (2023–2024 Formula) mRNA vaccine doses (i.e., Moderna, Pfizer-BioNTech) **OR** 2 updated (2023–2024 Formula) Novavax vaccine doses.
- Previously received 1 or 2 Original monovalent or bivalent mRNA vaccine doses: Complete the 3-dose series with 2 or 1 **homologous** updated (2023–2024 Formula) mRNA vaccine doses, respectively.
- Previously received a combined total of 3 or more Original monovalent or bivalent mRNA vaccine doses: 1 dose of any updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
- Previously received 1 or more Original monovalent Novavax vaccine doses, alone or in combination with any Original monovalent or bivalent mRNA vaccine doses: 1 dose of any updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
- Previously received 1 or more doses of Janssen vaccine, alone or in combination with any Original monovalent or bivalent mRNA vaccine or Original monovalent Novavax doses: 1 dose of any updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
- Additional doses: May receive 1 or more additional doses of an updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech) following the last recommended updated (2023–2024 Formula) COVID-19 vaccine dose.

People who were vaccinated for COVID-19 and subsequently become moderately or severely immunocompromised should follow the COVID-19 vaccination schedule according to their age and prior COVID-19 vaccination history (Table 2); see Considerations for timing of COVID-19 vaccination in relation to immunosuppressive therapies for vaccination of people who will shortly become moderately or severely immunocompromised (e.g., prior to organ transplant) and Considerations for COVID-19 revaccination.

Table 2. People who are moderately or severely immunocompromised: Recommended COVID-19 vaccination schedule by COVID-19 vaccination history, October 6, 2023

Updated (2023–2024 Formula) COVID-19 vaccines

Ages 6 months–4 years

COVID-19 vaccination history prior to updated (2023–2024 Formula) vaccine*	Updated (2023–2024 Formula) vaccine	Number of updated (2023–2024 Formula) doses indicated†	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses

COVID-19 vaccination history prior to updated (2023–2024 Formula) vaccine*	Updated (2023–2024 Formula) vaccine	Number of updated (2023–2024 Formula) doses indicated†	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
Unvaccinated	Moderna	3	0.25 mL/25 ug	Dark blue cap; green label	Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: At least 4 weeks

COVID-19 vaccination history prior to updated (2023–2024 Formula) vaccine*	Updated (2023–2024 Formula) vaccine	Number of updated (2023–2024 Formula) doses indicated†	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
	OR				
	Pfizer-BioNTech	3	0.3 mL/3 ug	Yellow cap; yellow label	Dose 1 and Dose 2: 3 weeks Dose 2 and Dose 3: At least 8 weeks
1 dose any Moderna	Moderna	2	0.25 mL/25 ug	Dark blue cap; green label	Dose 1: 4 weeks after last dose Dose 1 and Dose 2: At least 4 weeks
2 doses any Moderna	Moderna	1	0.25 mL/25 ug	Dark blue cap; green label	At least 4 weeks after last dose
3 or more doses any Moderna	Moderna	1	0.25 mL/25 ug	Dark blue cap; green label	At least 8 weeks after last dose
1 dose any Pfizer-BioNTech	Pfizer-BioNTech	2	0.3 mL/3 ug	Yellow cap; yellow label	Dose 1: 3 weeks after last dose Dose 1 and Dose 2: At least 8 weeks
2 doses any Pfizer-BioNTech	Pfizer-BioNTech	1	0.3 mL/3 ug	Yellow cap; yellow label	At least 8 weeks after last dose
3 or more doses any Pfizer-BioNTech	Pfizer-BioNTech	1	0.3 mL/3 ug	Yellow cap; yellow label	At least 8 weeks after last dose

*COVID-19 vaccination history refers to previous receipt of dose(s) of Original monovalent mRNA or bivalent mRNA vaccine or a combination of the two.

†Children ages 6 months–4 years who are moderately or severely immunocompromised have the option to receive 1 additional dose of a homologous updated (2023–2024 Formula) mRNA vaccine at least 2 months following the last recommended updated (2023–2024 Formula) mRNA vaccine dose. Further additional homologous updated (2023–2024 Formula) mRNA dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last updated (2023–2024 Formula) mRNA vaccine dose. For Moderna, administer 0.25 mL/25 ug (dark blue cap; green label); for Pfizer-BioNTech, administer 0.3 mL/3 ug (yellow cap; yellow label).

Ages 5–11 years*

COVID-19 vaccination history prior to updated (2023–2024 Formula) vaccine†	Updated (2023–2024 Formula) vaccine	Number of updated (2023–2024 Formula) doses indicated‡	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
Unvaccinated	Moderna	3	0.25 mL/25 ug	Dark blue cap; green label	Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: At least 4 weeks
	OR				
	Pfizer-BioNTech	3	0.3 mL/10 ug	Blue cap; blue label	Dose 1 and Dose 2: 3 weeks Dose 2 and Dose 3: At least 4 weeks
1 dose any Moderna	Moderna	2	0.25 mL/25 ug	Dark blue cap; green label	Dose 1: 4 weeks after last dose Dose 1 and Dose 2: At least 4 weeks
2 doses any Moderna	Moderna	1	0.25 mL/25 ug	Dark blue cap; green label	At least 4 weeks after last dose
1 dose any Pfizer-BioNTech	Pfizer-BioNTech	2	0.3 mL/10 ug	Blue cap; blue label	Dose 1: 3 weeks after last dose Dose 1 and Dose 2: At least 4 weeks
2 doses any Pfizer-BioNTech	Pfizer-BioNTech	1	0.3 mL/10 ug	Blue cap; blue label	At least 4 weeks after last dose
3 or more doses any mRNA vaccine	Moderna	1	0.25 mL/25 ug	Dark blue cap; green label	At least 8 weeks after last dose
	OR				
	Pfizer-BioNTech	1	0.3 mL/10 ug	Blue cap; blue label	At least 8 weeks after last dose

*The FDA EUA provides that children who transition from age 4 years to age 5 years during the Pfizer-BioNTech vaccination series complete the 3-dose series with updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vaccine for ages 6 months–4 years, 0.3 mL/3 ug (yellow cap; yellow label).

†COVID-19 vaccination history refers to previous receipt of dose(s) of Original monovalent mRNA or bivalent mRNA vaccine or a combination of the two.

‡Children ages 5–11 years who are moderately or severely immunocompromised have the option to receive 1 additional dose of updated (2023–2024 Formula) Moderna COVID-19 Vaccine, 0.25mL/25 ug (dark blue cap; green label) or updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL/10 ug (blue cap; blue label) at least 2 months following the last recommended updated (2023–2024 Formula) COVID-19 vaccine dose. Further additional dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last updated (2023–2024 Formula) COVID-19 vaccine dose.

Ages 12 years and older*

COVID-19 vaccination history prior to updated (2023–2024 Formula) vaccine†	Updated (2023–2024 Formula) vaccine	Number of updated (2023–2024 Formula) doses indicated‡	Dosage (mL/ug)	Vaccine vial cap and label colors§	Interval between doses
Unvaccinated	Moderna	3	0.5 mL/50 ug	Dark blue cap; blue label	Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: At least 4 weeks
	OR				
	Novavax	2	0.5 mL/5 ug rS protein and 50 ug Matrix-M adjuvant	Blue cap; blue label	Dose 1 and Dose 2: 3 weeks
	OR				
	Pfizer-BioNTech	3	0.3 mL/30 ug	Gray cap; gray label	Dose 1 and Dose 2: 3 weeks Dose 2 and Dose 3: At least 4 weeks
1 dose any Moderna	Moderna	2	0.5 mL/50 ug	Dark blue cap; blue label	Dose 1: 4 weeks after last dose Dose 1 and Dose 2: At least 4 weeks
2 doses any Moderna	Moderna	1	0.5 mL/50 ug	Dark blue cap; blue label	At least 4 weeks after last dose
1 dose any Pfizer-BioNTech	Pfizer-BioNTech	2	0.3 mL/30 ug	Gray cap; gray label	Dose 1: 3 weeks after last dose Dose 1 and Dose 2: At least 4 weeks
2 doses any Pfizer-BioNTech	Pfizer-BioNTech	1	0.3 mL/30 ug	Gray cap; gray label	At least 4 weeks after last dose
3 or more doses any mRNA vaccine	Moderna	1	0.5 mL/50 ug	Dark blue cap; blue label	At least 8 weeks after last dose
	OR				
	Novavax	1	0.5 mL/5 ug rS protein and 50 ug Matrix-M adjuvant	Blue cap; blue label	At least 8 weeks after last dose
	OR				
	Pfizer-BioNTech	1	0.3 mL/30 ug	Gray cap; gray label	At least 8 weeks after last dose
1 or more doses Novavax or Janssen, including in combination with any Original monovalent or bivalent COVID-19 vaccine doses	Moderna	1	0.5 mL/50 ug	Dark blue cap; blue label	At least 8 weeks after last dose
	OR				
	Novavax	1	0.5 mL/5 ug rS protein and 50 ug Matrix-M adjuvant	Blue cap; blue label	At least 8 weeks after last dose
	OR				
	Pfizer-BioNTech	1	0.3 mL/30 ug	Gray cap; gray label	At least 8 weeks after last dose

*Children who transition from age 11 years to age 12 years during the Moderna initial vaccination series are recommended to receive updated (2023–2024 Formula) Moderna COVID-19 Vaccine, 0.5 mL/50ug (dark blue cap; blue label) for all doses received on or after turning age 12 years. However, the FDA EUA provides that they may also receive the dosage for children ages 5–11 years, 0.25 mL/25ug (dark blue cap; blue label). Children who transition from age 11 years to age 12 years during the Pfizer-BioNTech initial vaccination series are recommended to receive updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL/30 ug (gray cap; gray label) for all doses received on or after turning age 12 years. However, the FDA EUA provides that they may also receive the dosage for children ages 5–11 years, 0.3 mL/10 ug (dark blue cap; green label).

†COVID-19 vaccination history refers to previous receipt of doses of Original monovalent mRNA or bivalent mRNA vaccine or a combination of the two; for people ages 12 years and older, Original monovalent Novavax COVID-19 Vaccine doses, alone or in combination with any mRNA vaccine doses; and for people ages 18 years and older, Janssen COVID-19 Vaccine doses, alone or in combination with any mRNA or Original monovalent Novavax vaccine doses.

[‡]Apart from the administration of additional doses, the FDA EUA for Novavax COVID-19 Vaccine does not provide for a specific vaccination schedule for people who are moderately or severely immunocompromised. People ages 12 years and older who are moderately or severely immunocompromised have the option to receive 1 additional dose of updated (2023–2024 Formula) Moderna COVID-19 Vaccine, 0.5 mL/50 ug (dark blue cap; blue label) updated (2023–2024 Formula) Novavax COVID-19 Vaccine; or updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL/30 ug (gray cap; gray label) at least 2 months following the last recommended updated (2023–2024 Formula) vaccine dose. Further additional doses may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last updated (2023–2024 Formula) COVID-19 vaccine dose.

[§]Updated (2023–2024 Formula) Moderna COVID-19 Vaccine and updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vaccine are also available in a prefilled, single-dose syringe for people ages 12 years and older.

Special situation: For people ages 6 months and older who are moderately or severely immunocompromised and received 1 dose of Moderna and 1 dose of Pfizer-BioNTech, see the section on Interchangeability for guidance on completing the initial vaccination series.

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
- Hematologic malignancies associated with poor responses to COVID-19 vaccines regardless of current treatment status (e.g., chronic lymphocytic leukemia, non-Hodgkin lymphoma, multiple myeloma, acute leukemia)
- Receipt of solid-organ transplant or an islet 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., common variable immunodeficiency disease, severe combined immunodeficiency, 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 (e.g., B-cell-depleting agents)

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.

For additional information about the degree of immune suppression associated with different medical conditions and treatments, providers can consult ACIP's General Best Practice Guidelines for Immunizations, the CDC Yellow Book, and the Infectious Diseases Society of America policy statement, 2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host.

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.

Considerations for COVID-19 revaccination

Recipients of HCT or CAR-T-cell therapy who received 1 or more doses of COVID-19 vaccine prior to or during treatment should be revaccinated. Revaccination should start at least 3 months (12 weeks) after transplant or CAR-T-cell therapy and should follow the currently recommended schedule for people who are unvaccinated (Table 2).

Revaccination may also be considered for patients who received 1 or more doses of COVID-19 vaccine during treatment with B-cell-depleting therapies (e.g., rituximab, ocrelizumab) that were administered over a limited period (e.g., as part of a treatment regimen for certain malignancies) according to the currently recommended schedule (Table 2). 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 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
- Individual benefits and risks

On a case-by-case basis, providers caring for these 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 who is immunocompromised.

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.

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Timing, spacing, age transitions, and simultaneous administration

4-Day grace period

Doses administered up to 4 days before the minimum interval or age, known as the 4-day grace period, are considered valid. If a dose is administered prior to the 4-day grace period, see Appendix B. Doses administered at any time after the recommended interval are valid.

Transitioning from a younger to older age group

In general, CDC recommends that people receive the age-appropriate vaccine product and dosage based on their age on the day of vaccination (Table 1 and Table 2).

If a person moves to an older age group between vaccine doses, they should receive the vaccine product and dosage for the older age group for all subsequent doses with one exception:

- The FDA EUA provides that children who transition from age 4 years to age 5 years during the Pfizer-BioNTech COVID-19 vaccination series complete the 3-dose series with updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vaccine for ages 6 months–4 years, 0.3 mL/3 ug (yellow cap; yellow label).

In addition, the FDA EUA provides that children who transition from age 4 years to age 5 years during the Moderna vaccination series complete the 2-dose series; there is no dosage change.

Simultaneous administration of COVID-19 vaccines with other vaccines

In accordance with General Best Practice Guidelines for Immunization, routine administration of all age-appropriate doses of vaccines simultaneously, also known as coadministration, is recommended for children, adolescents, and adults if there are no contraindications at the time of the healthcare visit. Simultaneous administration is defined as administering more than one vaccine on the same clinic day, at different anatomic sites, and not combined in the same syringe. Providers may simultaneously administer COVID-19, influenza, and respiratory syncytial virus (RSV) vaccines to eligible patients; the Health Alert Network (HAN) published on September 5, 2023 may be consulted for additional information about simultaneous administration of these vaccines.

There are additional considerations for simultaneous administration of an orthopoxvirus vaccine and COVID-19 vaccine as follows:

- There is no required minimum interval between receiving a dose of any COVID-19 vaccine and an orthopoxvirus vaccine, either JYNNEOS or ACAM2000 vaccine (e.g., for mpox prevention), regardless of which vaccine is administered first.
- Use of JYNNEOS vaccine should be prioritized over ACAM2000 when co-administering a COVID-19 vaccine and an orthopoxvirus vaccine.
- People, particularly adolescent or young adult males, who are recommended to receive both vaccines might consider waiting 4 weeks between vaccines. This is because of the observed risk for myocarditis and pericarditis after receipt of ACAM2000 orthopoxvirus vaccine and COVID-19 vaccines, and the hypothetical risk for myocarditis and pericarditis after JYNNEOS vaccine. However, if a patient's risk for mpox or severe disease due to COVID-19 is increased, administration of mpox and COVID-19 vaccines should not be delayed.

Nirsevimab: In accordance with General Best Practice Guidelines for Immunization, simultaneous administration of COVID-19 vaccine and nirsevimab (a long-acting monoclonal antibody for certain infants and young children for prevention of RSV) is recommended.

For best practices for administering multiple injections, see ACIP General Best Practice Guidelines for Immunization and *Epidemiology and Prevention of Vaccine-Preventable Diseases* (Pink Book).

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Interchangeability of COVID-19 vaccines

Interchangeability of mRNA COVID-19 vaccines

Children ages 6 months–4 years should receive all doses of an mRNA COVID-19 vaccine from the same manufacturer; this includes children who are moderately or severely immunocompromised and those who are not. People ages 5 years and older who are moderately or severely immunocompromised should receive a 3-dose initial mRNA vaccination series using vaccines from the same manufacturer.

For people who receive 1 Moderna and 1 Pfizer-BioNTech vaccine dose, complete the initial vaccination series as follows:

- Children ages 6 months–4 years who are not moderately or severely immunocompromised should follow a 3-dose schedule. A third dose of either updated (2023–2024 Formula) Moderna vaccine or updated (2023–2024 Formula) Pfizer-BioNTech vaccine should be administered at least 8 weeks after the second dose.
- People ages 6 months and older who are moderately or severely immunocompromised should follow the recommended 3-dose schedule. A third dose of either updated (2023–2024 Formula) Moderna vaccine or updated (2023–2024 Formula) Pfizer-BioNTech vaccine should be administered as follows:
  - Ages 6 months–4 years: at least 8 weeks after the second dose
  - Ages 5 years and older: at least 4 weeks after the second dose

Novavax COVID-19 Vaccine

People ages 12 years and older who receive a first dose of Novavax COVID-19 Vaccine should complete the 2-dose initial vaccination series with Novavax vaccine.

Exceptional situations

In the following exceptional situations, a different age-appropriate COVID-19 vaccine may be administered:

- Same vaccine not available
- Previous dose unknown
- Person would otherwise not complete the vaccination series
- Person starts but unable to complete a vaccination series with the same COVID-19 vaccine due to a contraindication

A Vaccine Adverse Event Reporting System (VAERS) report is not indicated for these exceptional situations.

The COVID-19 vaccination schedules for People who are **not** moderately or severely immunocompromised and People who are moderately or severely immunocompromised should be consulted for age-specific information; see Appendix B for recommended actions following interchangeability-related COVID-19 vaccine administration errors or deviations.

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Vaccination and SARS-CoV-2 laboratory testing

Pre-vaccination 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 is done, vaccination should be completed as recommended regardless of the antibody test result.

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).

See also CDC COVID-19 health care professional, CDC COVID-19 laboratory, and FDA SARS-CoV-2 laboratory testing Web pages.

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Patient counseling

Pre-vaccination counseling

Providers should counsel COVID-19 vaccine recipients, parents, or guardians about expected local and systemic reactions.

- Local reactions include pain/tenderness, and, less commonly, swelling, and erythema at the injection site.
- Systemic reactions include fever, fatigue/malaise, headache, chills, myalgia, arthralgia; among younger children, particularly those younger than age 3 years, systemic reactions also can include irritability/crying, sleepiness, and loss of appetite.

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 *(2)*. Infrequently, people who have received dermal fillers might experience temporary swelling at or near the site of filler injection (usually face or lips) following a dose of an mRNA COVID-19 vaccine.

Myocarditis and pericarditis: People receiving any COVID-19 vaccine, especially males ages 12–39 years, should be made aware of the rare risk of myocarditis and pericarditis following COVID-19 vaccination. 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 additional information.

Anaphylactic reactions: Anaphylactic reactions have been rarely reported following receipt of COVID-19 vaccines. For more information on the assessment and potential management of anaphylaxis, see Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination.

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

Post-vaccination observation period

Syncope (fainting) might occur in association with any injectable vaccine, especially in adolescents. In accordance with General Best Practice Guidelines for Immunization, vaccination providers, particularly when vaccinating adolescents, should consider observing vaccine recipients for 15 minutes after vaccination.

Additionally, to monitor for allergic reactions, providers should consider observing people with the following precautions to a previously administered COVID-19 vaccine type for 30 minutes if a subsequent dose of the same vaccine type is administered:

- History of a non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of one COVID-19 vaccine type
- History of a diagnosed non-severe allergy to a component of the COVID-19 vaccine

See Contraindications and precautions for more information.

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Contraindications and precautions

CDC considers the conditions listed in Table 3 to be COVID-19 vaccination contraindications and precautions.

Table 3. Contraindications and precautions to COVID-19 vaccination

Medical condition or history	Guidance	Recommended action
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 COVID-19 vaccine type.§ May administer the alternate COVID-19 vaccine type.§ See Considerations for people with a history of allergies and allergic reactions for additional information.
History of a diagnosed non-severe allergy* to a component of the COVID-19 vaccine‡	Precaution	May administer the alternate COVID-19 vaccine type.§ For additional information, see Considerations for people with a history of allergies and allergic reactions.
History of a non-severe, immediate (onset less than 4 hours) allergic reaction* after administration of a previous dose of one COVID-19 vaccine type§	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 within 3 weeks after a dose of **any COVID-19 vaccine**	Precaution	A subsequent dose of any COVID-19 vaccine should generally be avoided. See COVID-19 vaccination and myocarditis and pericarditis.

Abbreviations: MIS-C = multisystem inflammatory syndrome in children; MIS-A = multisystem inflammatory syndrome in adults

*Allergic reactions in Table 3 are defined as follows:

Severe allergic reactions include: known or possible anaphylaxis, a progressive life-threatening reaction that typically includes urticaria (hives) but also with other symptoms such as wheezing, difficulty breathing, or low blood pressure; angioedema (visible swelling) 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 but are not limited to: 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.

†Anaphylactic reactions have been rarely reported following receipt of COVID-19 vaccines (estimated incidence: 5 per million doses of mRNA COVID-19 vaccines administered). For more information on the assessment and potential management of anaphylaxis, see Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination.

‡See package inserts and FDA EUA fact sheets for a full list of vaccine ingredients. mRNA COVID-19 vaccines contain polyethylene glycol (PEG).

§The mRNA COVID-19 vaccines (Moderna and Pfizer-BioNTech) are one type of COVID-19 vaccine and the protein subunit vaccine (Novavax) is another type of COVID-19 vaccine.

Considerations for people with a history of allergies or allergic reactions

People with a contraindication to one COVID-19 vaccine type (Table 3) may receive the alternative COVID-19 vaccine type in the usual vaccination setting. Consultation with an allergist-immunologist is encouraged to provide expert evaluation of the original allergic reaction, and depending on the outcome of the evaluation, reassess if administration of additional doses of the same vaccine type may be possible.

People with an allergy-related precaution to one COVID-19 vaccine type (Table 3) may receive the alternative COVID-19 vaccine type in the usual vaccination setting. Vaccination with the same COVID-19 vaccine type may be considered on an individual basis; the same vaccine type should be administered in an appropriate setting and under the supervision of a health care provider experienced in the management of severe allergic reactions. An observation period of 30 minutes post-vaccination should be considered. Referral to an allergist-immunologist should be considered.

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.

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Reporting of vaccine adverse events

Adverse events that occur in a recipient following administration of any licensed or authorized COVID-19 vaccine should be reported to VAERS including:

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

Reporting is also 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.

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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. The most frequent reported reactions, by age group, follow below.

Older children, adolescents, and adults

- Local: Pain at the injection site; less commonly, redness and swelling
- Systemic: Fatigue, headache, and myalgia

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.

Younger children (ages 6 months–5 years)

- Local: Pain/tenderness at the injection site
- Systemic: Fatigue; in the youngest children (ages 6–23 months), irritability/crying and drowsiness/sleepiness

In all age groups, 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 simultaneous administration 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 and vaccine reactions and adverse events for Moderna and Pfizer-BioNTech mRNA COVID-19 vaccines.

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Safety considerations for Novavax COVID-19 Vaccine

In clinical trials of Novavax COVID-19 Vaccine, the most frequent reported vaccine reactions included:

- Local: Pain/tenderness at the injection site; less commonly, redness and swelling
- Systemic: Fatigue/malaise, headache, and muscle pain

Most symptoms were mild to moderate in severity, had onset 1-3 days after vaccination, 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 of the primary series. Among people ages 18 years and older who received the Novavax booster dose, symptoms were more frequently reported after the booster dose than dose 2 of the primary series.

See also COVID-19 vaccination and myocarditis and pericarditis and vaccine reactions and adverse events for Novavax COVID-19 Vaccine.

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COVID-19 vaccination and myocarditis and pericarditis

Considerations for COVID-19 vaccination

Cases of myocarditis and pericarditis have rarely been observed following receipt of COVID-19 vaccines used in the United States.

Evidence from multiple monitoring systems in the United States and globally support a causal association for mRNA COVID-19 vaccines (Moderna or Pfizer-BioNTech) and myocarditis and pericarditis. Cases have occurred most frequently in adolescent and young adult males within 7 days after receiving the second dose of an mRNA COVID-19 vaccine (Moderna and Pfizer-BioNTech); however, cases have also been observed in females and after other doses. Data from clinical trials of Novavax COVID-19 Vaccine and post-authorization vaccine safety monitoring outside the United States suggest an increased risk of myocarditis and pericarditis following Novavax vaccination.

For mRNA COVID-19 vaccines and Novavax COVID-19 Vaccine:

- After reviewing available data, ACIP and CDC determined that the benefits of COVID-19 vaccination (e.g., prevention of COVID-19 and its severe outcomes) outweigh the rare risk of myocarditis and pericarditis in all populations recommended for vaccination.
- Extending the interval to 8 weeks between the first and second doses for some people might reduce the rare risk of vaccine-associated myocarditis and pericarditis; see Considerations for extended intervals for COVID-19 vaccination for more information.
- People, 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 palpitations develop after vaccination, particularly in the week after vaccination.
  - In younger children, symptoms of myocarditis might also include non-specific symptoms such as irritability, vomiting, poor feeding, tachypnea, or lethargy.

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.

Myocarditis or pericarditis after a dose of COVID-19 vaccine

Development of myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine is a precaution to a subsequent dose of any COVID-19 vaccine, and subsequent doses should generally be avoided. Experts advise that these people should:

- Generally 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, wait until at least after their episode of myocarditis or pericarditis has resolved (resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by patient's clinical team)

Considerations for subsequent COVID-19 vaccination might include:

- Myocarditis or pericarditis considered unrelated to vaccination (e.g., due to SARS-CoV-2 or other viruses)
- 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

History of myocarditis or pericarditis that occurred prior to COVID-19 vaccination or more than 3 weeks after a COVID-19 vaccine dose

People who have a history of myocarditis or pericarditis that occurred before COVID-19 vaccination or more than 3 weeks after a COVID-19 vaccine dose may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved (i.e., resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by the person's clinical team). This includes people who had myocarditis or pericarditis due to SARS-CoV-2 or other viruses.

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

COVID-19 vaccines are not recommended for post-exposure prophylaxis. People with a known or potential SARS-CoV-2 exposure may receive vaccine if they do not have symptoms consistent with COVID-19; however, people should follow CDC's post-exposure guidance.

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, including people with prolonged post-COVID-19 symptoms.

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

People who recently had SARS-CoV-2 infection may consider delaying a COVID-19 vaccine dose by 3 months from symptom onset or positive test (if infection was asymptomatic). Studies have shown that increased time between infection and vaccination might 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 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.

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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. The risk of recurrence of MIS following reinfection with SARS-CoV-2 is unknown. It is also unknown if COVID-19 vaccination can, in rare instances, contribute to an MIS-like illness.

Considerations for initiating COVID-19 vaccination in 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 or MIS-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 recovery 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 or MIS-A

COVID-19 vaccination may also be considered for people who had MIS-C or MIS-A and **do not meet both criteria**, at the discretion of their clinical care team. 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.

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

Considerations for administration of subsequent COVID-19 doses in people diagnosed with MIS-C or MIS-A after COVID-19 vaccination

Onset of MIS more than 60 days after most recent COVID-19 vaccine dose

Administration of subsequent COVID-19 vaccine doses should be considered for those who meet the two recovery criteria described in Considerations for initiating COVID-19 vaccination in people with a history of MIS-C or MIS-A.

Onset of MIS 60 days or fewer after most recent COVID-19 vaccine dose

For persons in this category who meet the recovery criteria, the decision whether or not to administer subsequent COVID-19 vaccine doses should be made on an individual basis by the MIS clinical care team and patient or parent or guardian. Subsequent COVID-19 vaccine doses should especially be considered if there is strong evidence that the MIS-C or MIS-A was a complication of a recent SARS-CoV-2 infection.

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Considerations involving pregnancy, lactation, and fertility

Staying up to date with COVID-19 vaccinations is recommended for people who are pregnant, trying to get pregnant now, or who might become pregnant in the future, and people who are breastfeeding. A growing body of evidence on the safety and effectiveness of COVID-19 vaccination indicates that the benefits of vaccination outweigh any potential risks of COVID-19 vaccination during pregnancy. Maternal vaccination has also been shown to be safe and effective, and protects infants younger than age 6 months from severe COVID-19 and hospitalization.

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.

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Footnotes

1. 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.
2. The Society of Breast Imaging (SBI) has developed Revised SBI 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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Source: National Center for Immunization and Respiratory Diseases