Vaccines & Immunizations

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

Summary of recent changes (last updated October 31, 2024):

- People ages 65 years and older, vaccinated under the routine schedule, are recommended to receive 2 doses of any 2024–2025 COVID-19 vaccine (i.e., Moderna, Novavax, or Pfizer-BioNTech) separated by 6 months (minimum interval 2 months) regardless of vaccination history, with one exception: Unvaccinated people who initiate vaccination with 2024–2025 Novavax COVID-19 Vaccine are recommended to receive 2 doses of Novavax followed by a third dose of any COVID-19 vaccine 6 months (minimum interval 2 months) later.
- People ages 6 months and older who are moderately or severely immunocompromised are recommended to receive:
  - Unvaccinated: A multidose initial series with an age-appropriate COVID-19 vaccine and 1 dose 6 months (minimum interval 2 months) after completion of the initial series; may receive additional doses under shared clinical decision making
  - Previously completed the multidose initial series: 2 age-appropriate doses of 2024–2025 COVID-19 vaccine 6 months (minimum interval 2 months) apart; may receive additional doses under shared clinical decision making

Need information for consumers? Read about CDC's current COVID-19 vaccine recommendations.

Reference Materials

- COVID-19 Vaccine Product Information (Updated 9/27/24)

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What's this?

Overview of COVID-19 vaccines and 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
- The World Health Organization's (WHO) Emergency Use Listing (EUL) or Prequalification of COVID-19 vaccines
- ACIP's General Best Practice Guidelines for Immunization

COVID-19 vaccines

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

- mRNA vaccines
  - Moderna COVID-19 Vaccine (2024–2025 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 2024–2025 Moderna COVID-19 Vaccine.
  - Pfizer-BioNTech COVID-19 Vaccine (2024–2025 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 2024–2025 Pfizer-BioNTech COVID-19 Vaccine.
- Protein subunit vaccine
  - Novavax COVID-19 Vaccine, Adjuvanted (2024–2025 Formula) is authorized for people ages 12 years and older. It is hereafter referred to as 2024–2025 Novavax COVID-19 Vaccine.

The 2023–2024 Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines are no longer recommended and should not be used.

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.

COVID-19 vaccine composition

The 2024–2025 formulations for COVID-19 vaccines approved or authorized in the United States have been updated to a monovalent vaccine based on the Omicron JN.1-lineage of SARS-CoV-2, as follows:

- Moderna and Pfizer-BioNTech: KP.2 strain
- Novavax: JN.1 strain

COVID-19 vaccine-specific package inserts and EUA fact sheets for healthcare providers (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.

CDC recommends that people receive all recommended COVID-19 vaccine doses. Vaccination is especially important for people at highest risk of severe COVID-19, including people ages 65 years and older; people with underlying medical conditions, including immune compromise; people living in long-term care facilities; and pregnant people to protect themselves and their infants.

Vaccine dosage and administration

General Best Practice Guidelines for Immunization apply to COVID-19 vaccination unless otherwise noted. People should receive the age-appropriate vaccine product and dosage based on their age on the day of vaccination and follow the recommended dosing intervals (Table 1 and Table 2).

COVID-19 vaccine doses should be administered by the intramuscular route.

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Overview of the COVID-19 vaccination schedule

This section provides an overview of the recommendations for 2024–2025 COVID-19 vaccination. Detailed vaccination schedules, including age-appropriate vaccines, dosages, and intervals between doses, can be found in Table 1 for people vaccinated under the routine schedule (i.e., people who are not moderately or severely immunocompromised) and in Table 2 for people who are moderately or severely immunocompromised.

Routine COVID-19 vaccination

- Children ages 6 months–4 years
  - Unvaccinated: Should receive a multidose initial series with a 2024–2025 mRNA vaccine
  - Previously completed an initial series: Should receive 1 dose of a 2024–2025 mRNA vaccine from the same manufacturer as the initial series*
- People ages 5–64 years: Should receive 1 dose of an age-appropriate 2024–2025 COVID-19 vaccine†
- People ages 65 years and older: Should receive 2 doses of any 2024–2025 COVID-19 vaccine, spaced 6 months (minimum interval 2 months) apart‡

*For children ages 6 months–4 years who initiated but did not complete an initial series, consult Table 1.

†People ages 12–64 years who are unvaccinated and receive the 2024–2025 Novavax COVID-19 Vaccine for initial vaccination should receive 2 doses of 2024–2025 Novavax COVID-19 Vaccine.

‡People ages 65 years and older who are unvaccinated and receive Novavax COVID-19 Vaccine for initial vaccination should receive 2 doses of 2024–2025 Novavax COVID-19 Vaccine followed by a third dose of any 2024–2025 COVID-19 vaccine dose 6 months (minimum interval 2 months) after the second dose.

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

- Unvaccinated: Should receive a multidose initial series with an age-appropriate 2024–2025 COVID-19 vaccine and 1 dose of a 2024–2025 COVID-19 vaccine 6 months (minimum interval 2 months) after completing the initial series
- Previously completed an initial series: Should receive 2 doses of an age-appropriate 2024–2025 COVID-19 vaccine, spaced 6 months (minimum interval 2 months) apart*
- May receive additional age-appropriate 2024–2025 COVID-19 vaccine doses under shared clinical decision-making†

*For people ages 6 months and older who are moderately or severely immunocompromised who initiated but did not complete an initial series, consult Table 2.

†Additional doses may be administered, informed by the clinical judgment of a healthcare provider and personal preference and circumstances.

See Appendix A for recommendations for people who received COVID-19 vaccine outside the United States.

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Routine COVID-19 vaccination guidance

The routine COVID-19 vaccination schedule (i.e., for people who are not moderately or severely immunocompromised) is detailed in Table 1. The recommended vaccine and number of 2024–2025 COVID-19 vaccine doses are based on age and vaccination history. COVID-19 vaccination guidance for people who are moderately or severely immunocompromised is

detailed in Table 2.

Table 1. Routine COVID-19 vaccination schedule, October 31, 2024

Ages 6 months–4 years

NOTE: All COVID-19 vaccine doses in this age group should be from the same manufacturer; see Interchangeability of COVID-19 vaccines for information on circumstances in which vaccine from a different manufacturer may be considered.

COVID-19 vaccination history before 2024–2025 vaccine*	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine† and interval between doses
Unvaccinated: • Receive an initial series with 2024–2025 vaccine		
Unvaccinated	2	**2024–2025 Dose 1** (Moderna): Day 0 **2024–2025 Dose 2** (Moderna): 4–8 weeks after Dose 1‡
	OR	
	3	**2024–2025 Dose 1** (Pfizer-BioNTech): Day 0 **2024–2025 Dose 2** (Pfizer-BioNTech): 3–8 weeks after Dose 1‡ **2024–2025 Dose 3** (Pfizer-BioNTech): At least 8 weeks after Dose 2
Initiated but did not complete the initial series before 2024–2025 vaccine: • Complete the initial series with 2024–2025 vaccine		
1 dose Moderna	1	**2024–2025 Dose 1** (Moderna): 4–8 weeks after last dose‡
1 dose Pfizer-BioNTech	2	**2024–2025 Dose 1** (Pfizer-BioNTech): 3–8 weeks after last dose‡ **2024–2025 Dose 2** (Pfizer-BioNTech): At least 8 weeks after 2024–2025 Dose 1
2 doses Pfizer-BioNTech	1	**2024–2025 Dose 1** (Pfizer-BioNTech): At least 8 weeks after last dose
Completed the initial series before 2024–2025 vaccine: • Receive 1 dose of 2024–2025 vaccine		
2 or more doses Moderna	1	**2024–2025 Dose 1** (Moderna): At least 8 weeks after last dose
3 or more doses Pfizer-BioNTech	1	**2024–2025 Dose 1** (Pfizer-BioNTech): At least 8 weeks after last dose

*COVID-19 vaccination history refers to all doses of COVID-19 vaccine from any manufacturer received before the availability of the 2024–2025 COVID-19 vaccines and includes original, bivalent, and 2023–2024 COVID-19 vaccines.

†Dosage for Moderna: 0.25 mL/25 ug; dosage for Pfizer-BioNTech: 0.3 mL/3 ug.

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

Ages 5–11 years

NOTE: See footnote* for guidance on children who transition from age 4 years to age 5 years during the initial vaccination series.

COVID-19 vaccination history before 2024–2025 vaccine†	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine‡ and interval between doses
Unvaccinated: • Receive 1 dose of 2024–2025 vaccine		
Unvaccinated	1	**2024–2025 Dose 1** (Moderna or Pfizer-BioNTech): Day 0
Previously vaccinated before 2024–2025 vaccine: • Receive 1 dose of 2024–2025 vaccine		
1 or more doses mRNA (Moderna or Pfizer-BioNTech) vaccine	1	**2024–2025 Dose 1** (Moderna or Pfizer-BioNTech): At least 8 weeks after last dose

*Children who transition from age 4 years to age 5 years during the initial vaccination series should receive 1 dose of vaccine from the same manufacturer at the dosage for children ages 5–11 years on or after turning age 5 years:

- **Moderna**: 1 dose of 2024–2025 Moderna (0.25 mL/25 ug) 4–8 weeks after the first dose; there is no dosage change.
- **Pfizer-BioNTech**: 1 dose of 2024–2025 Pfizer-BioNTech (0.3 mL/10 ug). If the 10 ug dose is the second dose, administer 3–8 weeks after the first dose; if it is the third dose, administer at least 8 weeks after the second dose.
- **Note**: If more than 8 weeks have elapsed since receipt of the last dose of mRNA COVID-19 vaccine at the dosage for children ages 6 months–4 years, any 2024–2025 mRNA COVID-19 vaccine (i.e., Moderna or Pfizer-BioNTech) may be administered at the dosage for children ages 5–11 years.

[†]COVID-19 vaccination history refers to all doses of COVID-19 vaccine from any manufacturer recieved before the availability of the 2024–2025 COVID-19 vaccines and includes original, bivalent, and 2023–2024 COVID-19 vaccines.

[‡]Dosage for Moderna: 0.25 mL/25 ug; dosage for Pfizer-BioNTech: 0.3 mL/10 ug.

Ages 12–64 years

COVID-19 vaccination history before 2024–2025 vaccine[*†]	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine[‡] and interval between doses
Unvaccinated: • Initiate vaccination with 2024–2025 vaccine		
Unvaccinated	1	**2024–2025 Dose 1** (Moderna or Pfizer-BioNTech): Day 0
	OR	
	2	**2024–2025 Dose 1** (Novavax): Day 0 **2024–2025 Dose 2** (Novavax): 3–8 weeks after Dose 1[§]
Previously vaccinated before 2024–2025 vaccine: • Receive 1 dose of 2024–2025 vaccine		
1 or more doses mRNA (Moderna or Pfizer-BioNTech) vaccine	1	**2024–2025 Dose 1** (Moderna, Novavax or Pfizer-BioNTech): At least 8 weeks after last dose
1 dose Novavax	1	**2024–2025 Dose 1** (Novavax): 3–8 weeks after last dose[§¶]
2 or more doses Novavax	1	**2024–2025 Dose 1** (Moderna, Novavax or Pfizer-BioNTech): At least 8 weeks after last dose

*COVID-19 vaccination history refers to all doses of COVID-19 vaccine from any manufacturer received before the availability of the 2024–2025 COVID-19 vaccines and includes original, bivalent, and 2023–2024 COVID-19 vaccines.

[†]People ages 18-64 years who received 1 or more doses of Janssen COVID-19 Vaccine should receive 1 dose of any 2024–2025 COVID vaccine.

[‡]Dosage for Moderna: 0.5 mL/50 ug; dosage for Novavax: 0.5 mL/5 ug rS protein and 50 ug Matrix-M adjuvant; dosage for Pfizer-BioNTech: 0.3 mL/30 ug.

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

[¶]If more than 8 weeks have elapsed since receipt of the first dose of Novavax, any 2024–2025 COVID-19 vaccine (i.e., Moderna, Novavax, or Pfizer-BioNTech) may be administered.

Ages 65 years and older

COVID-19 vaccination history before 2024–2025 vaccine[*†]	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine[‡] and interval between doses
Unvaccinated: • Initiate vaccination with 2024–2025 vaccine		
Unvaccinated	2	**2024–2025 Dose 1** (Moderna or Pfizer-BioNTech): Day 0 **2024–2025 Dose 2** (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after Dose 1
	OR	
	3	**2024–2025 Dose 1** (Novavax): Day 0 **2024–2025 Dose 2** (Novavax): 3–8 weeks after Dose 1[§] **2024–2025 Dose 3** (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after Dose 2
Previously vaccinated before 2024–2025 vaccine: • Receive 2 doses of 2024–2025 vaccine		
1 or more doses mRNA vaccine (Moderna or Pfizer-BioNTech)	2	**2024–2025 Dose 1** (Moderna, Novavax or Pfizer-BioNTech): At least 8 weeks after last dose **2024–2025 Dose 2** (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 1
1 dose Novavax	2	**2024–2025 Dose 1** (Novavax): 3–8 weeks after last dose[§¶] **2024–2025 Dose 2** (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 1

COVID-19 vaccination history before 2024–2025 vaccine*†	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine‡ and interval between doses
2 or more doses Novavax	2	**2024–2025 Dose 1** (Moderna, Novavax or Pfizer-BioNTech): At least 8 weeks after last dose **2024–2025 Dose 2** (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 1

*COVID-19 vaccination history refers to all doses of COVID-19 vaccine from any manufacturer recevied before the availability of the 2024–2025 COVID-19 vaccines and includes original, bivalent, and 2023–2024 COVID-19 vaccines.

†People ages 65 years and older who received 1 or more doses of Janssen COVID-19 Vaccine should receive a first dose of any 2024–2025 COVID-19 vaccine followed by a second dose of any 2024–2025 COVID-19 vaccine 6 months (minimum interval 2 months) after the first dose.

‡Dosage for Moderna: 0.5 mL/50 ug; dosage for Novavax: 0.5 mL/5 ug rS protein and 50 ug Matrix-M adjuvant; dosage for Pfizer-BioNTech: 0.3 mL/30 ug.

§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 rare risk of myocarditis and pericarditis associated with these vaccines.

¶If more than 8 weeks have elapsed since receipt of the first dose of Novavax, any 2024–2025 COVID-19 vaccine (i.e., Moderna, Novavax, or Pfizer-BioNTech) may be administered.

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 rare 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 vaccinated under the routine schedule (i.e., not moderately or severely immunocompromised):

- Ages 6 months–4 years, depending on their vaccination history
- 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
- 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 ages 6 months and older who are moderately or severely immunocompromised is detailed in Table 2. The recommended vaccine and number of 2024–2025 COVID-19 vaccine doses are based on age and vaccination history. In all age groups, COVID-19 vaccine doses from the same manufacturer should be administered whenever recommended; see Interchangeability of COVID-19 vaccines for circumstances in which doses from different manufacturers may be considered.

For information on the use of pemivibart (Pemgarda™) for COVID-19 pre-exposure prophylaxis, see COVID-19 vaccination and pemivibart.

Table 2. COVID-19 vaccination schedule for people who are moderately or severely immunocompromised, October 31, 2024

Ages 6 months–4 years

NOTE: Children who are moderately or severely immunocompromised ages 6 months–4 years should receive all vaccine doses from the same manufacturer.

COVID-19 vaccination history before 2024–2025 vaccine*	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine† and interval between doses
Unvaccinated: • Receive an initial 3-dose series with 2024–2025 vaccine • Receive 1 dose of 2024–2025 vaccine 6 months (minimum interval 2 months) after completing initial series • May receive additional doses of 2024–2025 vaccine under shared clinical-decision making‡		
Unvaccinated	4	**2024–2025 Dose 1** (Moderna): Day 0 **2024–2025 Dose 2** (Moderna): 4 weeks after Dose 1 **2024–2025 Dose 3** (Moderna): At least 4 weeks after Dose 2 **2024–2025 Dose 4** (Moderna): 6 months (minimum interval 2 months) after Dose 3 **Additional doses** (Moderna): May be administered under shared clinical decision-making at least 2 months after last 2024–2025 Moderna dose‡
	OR	
	4	**2024–2025 Dose 1** (Pfizer-BioNTech): Day 0 **2024–2025 Dose 2** (Pfizer-BioNTech): 3 weeks after Dose 1 **2024–2025 Dose 3** (Pfizer-BioNTech): At least 8 weeks after Dose 2 **2024–2025 Dose 4** (Pfizer-BioNTech): 6 months (minimum interval 2 months) after Dose 3 **Additional doses** (Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last 2024–2025 Pfizer-BioNTech dose‡
Initiated but did not complete the 3-dose initial series before 2024–2025 vaccine: • Complete the 3-dose series with 2024–2025 vaccine • Receive 1 dose of 2024-2025 vaccine 6 months (minimum interval 2 months) after completing initial series • May receive additional doses of 2024–2025 vaccine under shared clinical-decision making‡		
1 dose Moderna	3	**2024–2025 Dose 1** (Moderna): 4 weeks after last dose **2024–2025 Dose 2** (Moderna): At least 4 weeks after 2024–2025 Dose 1 **2024–2025 Dose 3** (Moderna): 6 months (minimum interval 2 months) after 2024–2025 Dose 2 **Additional doses** (Moderna): May be administered under shared clinical-decision making at least 2 months after last 2024–2025 Moderna dose‡
2 doses Moderna	2	**2024–2025 Dose 1** (Moderna): At least 4 weeks after last dose **2024–2025 Dose 2** (Moderna): 6 months (minimum interval 2 months) after 2024–2025 Dose 1 **Additional doses** (Moderna): May be administered under shared clinical decision-making at least 2 months after last 2024–2025 Moderna dose‡
1 dose Pfizer-BioNTech	3	**2024–2025 Dose 1** (Pfizer-BioNTech): 3 weeks after last dose **2024–2025 Dose 2** (Pfizer-BioNTech): At least 8 weeks after 2024–2025 Dose 1 **2024–2025 Dose 3** (Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 2 **Additional doses** (Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last 2024–2025 Pfizer-BioNTech dose‡

COVID-19 vaccination history before 2024–2025 vaccine*	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine† and interval between doses
2 doses Pfizer-BioNTech	2	**2024–2025 Dose 1** (Pfizer-BioNTech): At least 8 weeks after last **2024–2025 Dose 2** (Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 1 **Additional doses** (Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last 2024–2025 Pfizer-BioNTech dose‡
Completed the 3-dose initial series before 2024–2025 vaccine: • Receive 2 doses of 2024–2025 vaccine spaced 6 months (minimum interval 2 months) apart • May receive additional doses of 2024–2025 vaccine under shared clinical-decision making‡		
3 or more doses Moderna	2	**2024–2025 Dose 1** (Moderna): At least 8 weeks after last dose **2024–2025 Dose 2** (Moderna): 6 months (minimum interval 2 months) after 2024–2025 Dose 1 **Additional doses** (Moderna): May be administered under shared clinical decision-making at least 2 months after last 2024–2025 Moderna dose‡
3 or more doses Pfizer-BioNTech	2	**2024–2025 Dose 1** (Pfizer-BioNTech): At least 8 weeks after last dose **2024–2025 Dose 2** (Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 1 **Additional doses** (Pfizer-BioNTech): May be administered under shared clinical-decision making at least 2 months after last 2024–2025 Pfizer-BioNTech dose‡

*COVID-19 vaccination history refers to all doses of COVID-19 vaccine from any manufacturer received before the availability of the 2024–2025 COVID-19 vaccines, and includes original, bivalent, and 2023–2024 COVID-19 vaccines.

†Dosage for Moderna: 0.25 mL/25 ug; dosage for Pfizer-BioNTech: 0.3 mL/3 ug.

‡Additional doses may be administered, informed by the clinical judgment of a healthcare provider and personal preference and circumstances.

Ages 5–11 years

NOTE: See footnote* for guidance on children who transition from age 4 years to age 5 years during the initial vaccination series.

COVID-19 vaccination history before 2024–2025 vaccine†	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine‡ and interval between doses
Unvaccinated: • Receive an initial 3-dose series with 2024–2025 vaccine • Receive 1 dose of 2024–2025 vaccine 6 months (minimum interval 2 months) after completing initial series • May receive additional doses of 2024–2025 vaccine under shared clinical-decision making§		
Unvaccinated	4	**2024–2025 Dose 1** (Moderna): Day 0 **2024–2025 Dose 2** (Moderna): 4 weeks after Dose 1 **2024–2025 Dose 3** (Moderna): At least 4 weeks after Dose 2 **2024–2025 Dose 4** (Moderna or Pfizer-BioNTech): 6 months (minimum interval 2 months) after Dose 3 **Additional doses** (Moderna or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last 2024–2025 mRNA dose§
	OR	
	4	**2024–2025 Dose 1** (Pfizer-BioNTech): Day 0 **2024–2025 Dose 2** (Pfizer-BioNTech): 3 weeks after Dose 1 **2024–2025 Dose 3** (Pfizer-BioNTech): At least 4 weeks after Dose 2 **2024–2025 Dose 4** (Moderna or Pfizer-BioNTech): 6 months (minimum interval 2 months) after Dose 3 **Additional doses** (Moderna or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last 2024–2025 mRNA dose§
Initiated but did not complete the 3-dose initial series before 2024–2025 vaccine: • Complete the 3-dose series with 2024–2025 vaccine • Receive 1 dose of 2024–2025 vaccine 6 months (minimum interval 2 months) after completing initial series • May receive additional doses of 2024–2025 vaccine under shared clinical decision-making§		

COVID-19 vaccination history before 2024–2025 vaccine[†]	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine[‡] and interval between doses
1 dose Moderna	3	**2024–2025 Dose 1** (Moderna): 4 weeks after last dose **2024–2025 Dose 2** (Moderna): At least 4 weeks after 2024–2025 Dose 1 **2024–2025 Dose 3** (Moderna or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 2 **Additional doses** (Moderna or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last 2024–2025 mRNA dose[§]
2 doses Moderna	2	**2024–2025 Dose 1** (Moderna): At least 4 weeks after last dose **2024–2025 Dose 2** (Moderna or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 1 **Additional doses** (Moderna or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last 2024–2025 mRNA dose[§]
1 dose Pfizer-BioNTech	3	**2024–2025 Dose 1** (Pfizer-BioNTech): 3 weeks after last dose **2024–2025 Dose 2** (Pfizer-BioNTech): At least 4 weeks after 2024–2025 Dose 1 **2024–2025 Dose 3** (Moderna or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 2 **Additional doses** (Moderna or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last 2024–2025 mRNA dose[§]
2 doses Pfizer-BioNTech	2	**2024–2025 Dose 1** (Pfizer-BioNTech): At least 4 weeks after last dose **2024–2025 Dose 2** (Moderna or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 2 **Additional doses** (Moderna or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last 2024–2025 mRNA dose[§]
Completed the 3-dose initial series before 2024–2025 vaccine: • Receive 2 doses of 2024–2025 vaccine spaced 6 months (minimum interval 2 months) apart • May receive additional doses of 2024–2025 vaccine under shared clinical decision-making[§]		
3 or more doses Moderna or 3 or more doses Pfizer-BioNTech[¶]	2	**2024–2025 Dose 1** (Moderna or Pfizer-BioNTech): At least 8 weeks after last dose **2024–2025 Dose 2** (Moderna or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 1 **Additional doses** (Moderna or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last 2024–2025 mRNA dose[§]

*Children who transition from age 4 years to age 5 years during the initial vaccination series should complete the 3-dose series using the dosage for children ages 5–11 years for all doses received on or after turning age 5 years:

- Moderna series: 2024–2025 Moderna, 0.25 mL/25 ug; there is no dosage change
- Pfizer-BioNTech series: 2024–2025 Pfizer-BioNTech, 0.3 mL/10 ug

[†]COVID-19 vaccination history refers to all doses of COVID-19 vaccine from any manufacturer received before the availability of the 2024–2025 COVID-19 vaccines and includes original, bivalent, and 2023–2024 COVID-19 vaccines.

[‡]Dosage for Moderna: 0.25 mL/25 ug; dosage for Pfizer-BioNTech: 0.3 mL/10 ug.

[§]Additional doses may be administered, informed by the clinical judgment of a healthcare provider and personal preference and circumstances.

[¶]This COVID-19 vaccine history refers to previous receipt of 3 doses of mRNA vaccine from the same manufacturer (i.e., Moderna or Pfizer-BioNTech) for initial vaccination followed by 1 or more additional doses of any mRNA vaccine.

Ages 12 years and older

NOTE: See footnote* for guidance on children who transition from age 11 years to age 12 years during the initial vaccination series.

COVID-19 vaccination history before 2024–2025[†‡]	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine[§] and interval between doses
Unvaccinated: • Receive an initial series with 2024–2025 vaccine • Receive 1 dose of 2024–2025 vaccine 6 months (minimum interval 2 months) after completing initial series • May receive additional doses of 2024–2025 vaccine under shared clinical decision-making[¶]		

COVID-19 vaccination history before 2024–2025[†‡]	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine[§] and interval between doses
Unvaccinated	4	**2024–2025 Dose 1** (Moderna): Day 0 **2024–2025 Dose 2** (Moderna): 4 weeks after Dose 1 **2024–2025 Dose 3** (Moderna): At least 4 weeks after Dose 2 **2024–2025 Dose 4** (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after Dose 3 **Additional doses** (Moderna, Novavax, or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024–2025 vaccine[¶]
	OR	
	3	**2024–2025 Dose 1** (Novavax): Day 0 **2024–2025 Dose 2** (Novavax): 3 weeks after Dose 1 **2024–2025 Dose 3** (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after Dose 2 **Additional doses**: (Moderna, Novavax, or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024–2025 vaccine[¶]
	OR	
	4	**2024–2025 Dose 1** (Pfizer-BioNTech): Day 0 **2024–2025 Dose 2** (Pfizer-BioNTech): 3 weeks after Dose 1 **2024–2025 Dose 3** (Pfizer-BioNTech): At least 4 weeks after Dose 2 **2024–2025 Dose 4** (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after Dose 3 **Additional doses** (Moderna, Novavax, or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024–2025 vaccine[¶]
Initiated but did not complete the initial series before 2024–2025 vaccine: • Complete the initial series with 2024–2025 vaccine • Receive 1 dose of 2024–2025 vaccine 6 months (minimum interval 2 months) after completing initial series • May receive additional doses of 2024–2025 vaccine under shared clinical decision-making[¶]		
1 dose Moderna	3	**2024–2025 Dose 1** (Moderna): 4 weeks after last dose **2024–2025 Dose 2** (Moderna): At least 4 weeks after 2024–2025 Dose 1 **2024–2025 Dose 3** (Moderna, Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 2 **Additional doses** (Moderna, Novavax, or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024–2025 vaccine[¶]
2 doses Moderna	2	**2024–2025 Dose 1** (Moderna): At least 4 weeks after last dose **2024–2025 Dose 2** (Moderna, Novavax or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 1 **Additional doses** (Moderna, Novavax or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024–2025 vaccine[¶]
1 dose Pfizer-BioNTech	3	**2024–2025 Dose 1** (Pfizer-BioNTech): 3 weeks after last dose **2024–2025 Dose 2** (Pfizer-BioNTech): At least 4 weeks after 2024–2025 Dose 1 **2024–2025 Dose 3** (Moderna, Novavax or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 2 **Additional doses** (Moderna, Novavax or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024–2025 vaccine[¶]
2 doses Pfizer-BioNTech	2	**2024–2025 Dose 1** (Pfizer-BioNTech): At least 4 weeks after last dose **2024–2025 Dose 2** (Moderna, Novavax or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 1 **Additional doses** (Moderna, Novavax or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024–2025 vaccine[¶]
1 dose Novavax	2	**2024–2025 Dose 1** (Novavax): At least 3 weeks after last dose **2024–2025 Dose 2** (Moderna, Novavax or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 1 **Additional doses** (Moderna, Novavax or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024–2025 vaccine[¶]
Completed the initial series before 2024–2025 vaccine: • Receive 2 doses of 2024–2025 vaccine spaced 6 months (minimum interval 2 months) apart • May receive additional doses of 2024–2025 vaccine under shared clinical decision-making[¶]		
3 or more doses Moderna or 3 or more doses Pfizer-BioNTech[#]	2	**2024–2025 Dose 1** (Moderna, Novavax or Pfizer-BioNTech): At least 8 weeks after last dose **2024–2025 Dose 2** (Moderna, Novavax or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 1 **Additional doses** (Moderna, Novavax or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024–2025 vaccine[¶]

COVID-19 vaccination history before 2024–2025[†‡]	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine[§] and interval between doses
2 or more doses Novavax[#]	2	**2024–2025 Dose 1** (Moderna, Novavax or Pfizer-BioNTech): At least 8 weeks after last dose **2024–2025 Dose 2** (Moderna, Novavax or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2024–2025 Dose 1 **Additional doses** (Moderna, Novavax or Pfizer-BioNTech): May be administered under shared clinical decision-making at least 2 months after last dose any 2024–2025 vaccine[¶]

*Children who transition from age 11 years to age 12 years during the initial vaccination series should complete the 3-dose series using the dosage for people ages 12 years and older for all doses received on or after turning age 12 years:

- Moderna series: 2024–2025 Moderna, 0.5 mL/50ug
- Pfizer-BioNTech series: 2024–2025 Pfizer-BioNTech, 0.3 mL/30 ug

[†]COVID-19 vaccination history refers to all doses of COVID-19 vaccine from any manufacturer received before the availability of the 2024–2025 COVID-19 vaccines and includes original, bivalent, and 2023–2024 COVID-19 vaccines.

[‡]People ages 18 years and older who received 1 or more doses of Janssen COVID-19 Vaccine should receive 1 dose of any 2024–2025 COVID-19 followed by a second dose of any 2024–2025 COVID-19 vaccine 6 months (minimum interval 2 months) after the first dose. Additional doses of any 2024–2025 COVID-19 vaccine may be administered under shared clinical decision-making at least 2 months after last dose of any 2024–2025 vaccine.

[§]Dosage for Moderna: 0.5 mL/50 ug; dosage for Novavax: 0.5 mL/5 ug rS protein and 50 ug Matrix-M adjuvant; dosage for Pfizer-BioNTech: 0.3 mL/30 ug.

[¶]Additional doses may be administered, informed by the clinical judgment of a healthcare provider and personal preference and circumstances.

[#]This COVID-19 vaccine history refers to previous receipt of 3 doses of mRNA vaccine from the same manufacturer (i.e., Moderna or Pfizer-BioNTech) for initial vaccination or 2 doses of Novavax for initial vaccination followed by 1 or more additional doses of any COVID-19 vaccine.

Development of moderate or severe immunocompromise after vaccination: 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.

COVID-19 vaccination and pemivibart

Pemivibart (Pemgarda™) is a monoclonal antibody for COVID-19 pre-exposure prophylaxis in people who are moderately or severely immunocompromised and unlikely to mount an adequate immune response to COVID-19 vaccination and who meet the FDA-authorized conditions for use . Pemivibart is not authorized for treatment of COVID-19 or for post-exposure prophylaxis. Healthcare providers should consult the pemivibart fact sheet and frequently asked questions for additional information.

Pemivibart is not a substitute for COVID-19 vaccination. People who are moderately or severely immunocompromised should receive COVID-19 vaccine according to the recommended schedule. Per the pemivibart EUA , administration of pemivibart should be deferred for at least 2 weeks after a dose of COVID-19 vaccine.

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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Age transitions and simultaneous administration

Transitioning from a younger to older age group

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 children who transition from age 4 years to age 5 years and children who are moderately or severely immunocompromised and transition from age 11 years to age 12 years, the option to administer a lower dosage is no longer authorized (see Table 1 and Table 2).

Simultaneous administration of COVID-19 vaccines with other vaccines

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.

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: Simultaneous administration of COVID-19 vaccine and nirsevimab (a long-acting monoclonal antibody indicated for certain infants and young children for prevention of RSV lower respiratory tract disease) 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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Administration of COVID-19 vaccine doses from different manufacturers

COVID-19 vaccine doses from the same manufacturer should be administered whenever recommended. In the following circumstances, an age-appropriate COVID-19 vaccine from a different manufacturer may be administered:

- Same vaccine not available at the time of the clinic visit
- Previous dose unknown
- Person would otherwise not receive a recommended vaccine dose
- 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 in these circumstances.

mRNA COVID-19 vaccines

If mRNA vaccine doses are administered from different manufacturers because of a circumstance described above, a 3-dose schedule for initial vaccination should be followed:

Children ages 6 months–4 years

- The second dose is administered 4–8 weeks after the first dose.
- The third dose of either 2024–2025 Moderna vaccine or 2024–2025 Pfizer-BioNTech vaccine is administered at least 8 weeks after the second dose.

People ages 6 months and older who are moderately or severely immunocompromised

- The second dose is administered 4 weeks after the first dose.
- The third dose of either 2024–2025 Moderna vaccine or 2024–2025 Pfizer-BioNTech vaccine is 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 are initiating vaccination with Novavax COVID-19 Vaccine (i.e., previously unvaccinated) and receive a first dose of Novavax should complete the 2-dose initial vaccination series with Novavax vaccine. However, if more than 8 weeks have elapsed since receipt of the first dose of Novavax, any 2024–2025 COVID-19 vaccine (i.e., Moderna, Novavax, or Pfizer-BioNTech) may be administered under routine vaccination.

See Appendix B for additional information if doses from different manufacturers are administered for initial vaccination.

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COVID-19 vaccination and SARS-CoV-2 laboratory 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 or SARS-CoV2 infection. If antibody testing is done, vaccination should proceed as recommended regardless of the antibody test result.

COVID-19 vaccination will not affect the results of SARS-CoV-2 viral tests (nucleic acid amplification or antigen tests).

For more information see Overview of Testing for SARS-CoV-2 and the FDA Web page on serologic testing .

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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 redness at the injection site.
- Systemic reactions include fever, fatigue/malaise, headache, chills, myalgia, arthralgia, and diarrhea; 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. 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 and the option for an extended interval between doses. 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 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 CDC's 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

For licensed COVID-19 vaccines (Moderna and Pfizer-BioNTech in people ages 12 years and older), healthcare providers are strongly encouraged to report to VAERS :

- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether or not it is clear that a vaccine caused the adverse event
- Vaccine administration errors, whether or not associated with an adverse event

For COVID-19 vaccines given under an EUA, vaccination providers are **required** to report to VAERS :

- Vaccine administration errors, whether or not associated with an adverse event
- Serious adverse events regardless of causality. Serious adverse events per FDA are defined as:
  - Death
  - A life-threatening adverse event
  - Inpatient hospitalization or prolongation of existing hospitalization
  - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
  - A congenital anomaly/birth defect
  - An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above
- Cases of Multisystem Inflammatory Syndrome (MIS) in children and adults
- 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. In addition, anyone can register in V-safe after their COVID-19 vaccination to receive health check-ins via text messages or email.

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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. However, the frequency of some reactions varied by age, vaccine manufacturer, and vaccine dose. The most frequent reported reactions, by age group, follow below.

People ages 12 years and older

- Local: Injection site pain; less commonly, injection site redness and swelling, and axillary swelling/tenderness
- Systemic: Fatigue, headache, myalgia, arthralgia, and chills; less commonly, fever and nausea/vomiting

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.

Children ages 6 months–11 years

- Local: Injection site pain/tenderness; less commonly, injection site redness and swelling, and axillary or groin swelling/tenderness
- Systemic:
  - Ages 6 months–4 years: Irritability/crying, drowsiness/sleepiness, and decreased/loss of appetite, particularly in children younger than age 3 years; less commonly, fever
  - Ages 5–11 years: Fatigue and headache; less commonly, myalgia, arthralgia, fever, chills, diarrhea, and nausea/vomiting

In all age groups, most symptoms were mild to moderate in severity, typically began 1–2 days after vaccination, and resolved after 1–3 days.

EUA fact sheets and package inserts can be consulted for detailed information about post-vaccination reactions for Moderna and Pfizer-BioNTech COVID-19 vaccines.

Febrile seizures in infants and young children occur infrequently after any vaccination; one febrile seizure was reported among participants ages 6 months–23 months in Moderna's COVID-19 clinical trial . CDC postmarketing safety surveillance for mRNA COVID-19 vaccines has not identified a safety concern for febrile seizure in children ages 6 months–5 years. The potential impact of simultaneous administration of COVID-19 and routine vaccines on the risk of febrile seizures has not been specifically studied. CDC is continuing to monitor 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 among people ages 12 years and older, the most frequent reported vaccine reactions included:

- Local: Pain/tenderness at the injection site; less commonly, redness and swelling
- Systemic: Fatigue/malaise, headache, and myalgia; less commonly, arthralgia, nausea/vomiting, and fever

In addition, lymphadenopathy was also reported to occur after Novavax vaccination in the clinical trials.

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 initial vaccination series.

The EUA fact sheet can be consulted for detailed information about post-vaccination reactions for Novavax COVID-19 Vaccine.

See also COVID-19 vaccination and myocarditis and pericarditis.

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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 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; the option for an extended interval between doses; 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 within 3 weeks 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 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

Myocarditis or pericarditis before 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 prior SARS-CoV-2 infection

COVID-19 vaccination is recommended for everyone ages 6 months and older, regardless of prior symptomatic or asymptomatic SARS-CoV-2 infection, including people with Long COVID.

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 generally been observed in the months following infection. Individual factors such as risk of severe COVID-19 and current indicators of community transmission should be taken into account when determining whether to delay getting a COVID-19 vaccination after infection.

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

MIS-C and MIS-A are rare and potentially serious post-infectious complications of SARS-CoV-2 infection. Both are associated with a dysregulated immune response to SARS-CoV-2 infection. MIS-C incidence has declined by more than 90% since the start of the pandemic despite continued SARS-CoV-2 infections and re-infections.

There have been rare reports of MIS-like illness after COVID-19 vaccination identified from U.S. surveillance (<1 MIS-C case per million vaccinated children without laboratory evidence of SARS-CoV-2 infection). However, the contribution of COVID-19 vaccination to an MIS-like illness is unknown.

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 rare 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.

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 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

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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Last Reviewed: October 31, 2024