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

AT A GLANCE

- These clinical considerations inform healthcare professionals and public health officials on use of COVID-19 vaccines.
- The Table of Contents on each page can be used to navigate to all guidance pages.
- A PDF version of the complete clinical considerations is available below to download and print.

Table of Contents

Summary of recent changes

Last updated May 1, 2025

- The Interim Clinical Considerations have been divided into multiple pages by guidance topic to enhance usability.
- Vaccination guidance and schedules are unchanged; some text has been reformatted and reorganized.

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Implementation resources

- COVID-19 Vaccine Product Information (Updated 9/27/24)
- 2024–2025 COVID-19 Vaccination Guidance for People 6 Months of Age and Older (Updated 3/14/25)
- Shared Clinical Decision-Making: Additional Doses of COVID-19 Vaccine for People Who Are Moderately or Severely Immunocompromised (1/20/2025)

Overview of COVID-19 Vaccines and Vaccination

AT A GLANCE

- COVID-19 vaccination is recommended for people ages 6 months and older.
- Two types of COVID-19 vaccines are recommended for use in the United States: mRNA vaccines (Moderna and Pfizer-BioNTech) and a protein subunit vaccine (Novavax).
- There are two COVID-19 vaccine schedules: a routine schedule and a specific schedule for people who are moderately or severely immunocompromised.

Introduction

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 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
- General Best Practices for Immunization

Types of 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 women to protect themselves and their infants.

Vaccine dosage and administration

General Best Practices 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.

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.

For recommendations for people who were vaccinated outside the United States, see page on Special Situations and Populations.

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.
    - Initiated but did not complete an initial series: Consult Table 1.
- People ages 5–64 years:
    - Should receive 1 dose of an age-appropriate 2024–2025 COVID-19 vaccine.
    - 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:
    - Should receive 2 doses of any 2024–2025 COVID-19 vaccine, spaced 6 months (minimum interval 2 months) apart.
    - 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.
- Initiated but did not complete an initial series: Consult Table 2.
- May receive additional age-appropriate 2024–2025 COVID-19 vaccine doses under shared clinical decision-making.

Routine COVID-19 Vaccination Guidance

AT A GLANCE

- The routine COVID-19 vaccination schedule is recommended for people ages 6 months and older who are not moderately or severely immunocompromised.
- The recommended vaccine and number of doses are based on age and vaccination history.
- An extended interval between the first and second dose of COVID-19 vaccine may be considered in some situations.

Introduction

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

1a: 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		

COVID-19 vaccination history before 2024–2025 vaccine*	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine† and interval between doses
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.

1b: 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 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.

1c: 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.

1d: 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		

COVID-19 vaccination history before 2024–2025 vaccine*†	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine‡ and interval between doses
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
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 received 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)

COVID-19 Vaccination Guidance for People Who Are Immunocompromised

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- There is a specific COVID-19 vaccination schedule for people who are moderately or severely immunocompromised.
- People can self-attest to being moderately or severely immunocompromised and receive COVID-19 vaccine doses where available.
- Administering COVID-19 vaccines should not be delayed in patients taking immunosuppressive therapies.

Introduction

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. People who are moderately or severely immunocompromised also have the option to receive additional doses of 2024–2025 COVID-19 vaccine under shared clinical decision-making after receiving all the recommended doses of 2024–2025 COVID-19 vaccine.

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

2a: 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	

COVID-19 vaccination history before 2024–2025 vaccine*	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine† and interval between doses
	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

COVID-19 vaccination history before 2024–2025 vaccine*	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine† and interval between doses
		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‡
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

COVID-19 vaccination history before 2024–2025 vaccine*	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine† and interval between doses
		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.

2b: 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.

<table>
<tr><th>COVID-19 vaccination history before 2024–2025 vaccine[†]</th><th>Number of 2024–2025 doses indicated</th><th>Recommended 2024–2025 vaccine[‡] and interval between doses</th></tr>
<tr><td colspan="3">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[§]</td></tr>
<tr><td rowspan="3">Unvaccinated</td><td>4</td><td>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[§]</td></tr>
<tr><td colspan="2">OR</td></tr>
<tr><td>4</td><td>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[§]</td></tr>
</table>

COVID-19 vaccination history before 2024–2025 vaccine[†]	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine[‡] and interval between doses
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 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

COVID-19 vaccination history before 2024–2025 vaccine[†]	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine[‡] and interval between doses
		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.

2c: 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[¶]		
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

COVID-19 vaccination history before 2024–2025[†‡]	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine[§] and interval between doses
		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:		

COVID-19 vaccination history before 2024–2025[†‡]	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine[§] and interval between doses
• 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

COVID-19 vaccination history before 2024–2025[†‡]	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine[§] and interval between doses
		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

COVID-19 vaccination history before 2024–2025[†‡]	Number of 2024–2025 doses indicated	Recommended 2024–2025 vaccine[§] and interval between doses
		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 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 Food and Drug Administration (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 Emergency Use Authorization (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 General Best Practices 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.

Implementation Guidance

AT A GLANCE

- Implementation guidance addresses practical issues that may arise during COVID-19 vaccination including simultaneous administration and interchangeability.
- Pre-vaccination patient counseling should include information on potential local and systemic reactions.

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 respiratory syncytial virus [RSV] lower respiratory tract disease) is recommended.

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

Interchangeability of COVID-19 vaccines

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

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 Food and Drug Administration web page on serologic testing.

Pre-vaccination counseling

Providers should counsel COVID-19 vaccine recipients, parents, or guardians about potential 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 Practices 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 Considerations for people with a history of allergies or allergic reactions for more information.

Contraindications and Precautions

AT A GLANCE

- Providers should screen patients for contraindications and precautions to COVID-19 vaccination before administering a vaccine dose.
- CDC considers the conditions listed in Table 3 to be COVID-19 vaccination contraindications and precautions.
- There are additional considerations for people with a history of allergies or allergic reactions

General principles

Healthcare providers who administer vaccines should screen patients for contraindications and precautions to the vaccine before each dose of vaccine is administered. 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.§
History of a non-severe, immediate (onset less than 4 hours) allergic reaction* after	Precaution	For additional information, see Considerations for people with a

Medical condition or history	Guidance	Recommended action
administration of a previous dose of one COVID-19 vaccine type[§]		history of allergies and allergic reactions.
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 Emergency Use Authorization (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 (CISA) Project for a complex COVID-19 vaccine safety question not readily addressed by CDC guidance.

Safety Considerations for COVID-19 Vaccines

AT A GLANCE

- In COVID-19 vaccine clinical trials, most local and systemic post-vaccination reactions were mild to moderate and resolved in 1–3 days.
- Myocarditis and pericarditis are rarely observed after COVID-19 vaccination.

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.

Emergency Use Authorization (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.

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.

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, the Advisory Committee on Immunization Practices (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 multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (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; General Best Practices 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 Food and Drug Administration (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.

Reporting of Vaccine Adverse Events

AT A GLANCE

- Reporting to the Vaccine Adverse Event Reporting System (VAERS) differs for licensed COVID-19 vaccines and COVID-19 vaccines given under an Emergency Use Authorization (EUA).
- Information on reporting adverse events to VAERS and how to register in V-safe is provided.

Licensed COVID-19 vaccines

For licensed COVID-19 vaccines (Moderna and Pfizer-BioNTech in people ages 12 years and older), healthcare providers are strongly encouraged to report to the Vaccine Adverse Event Reporting System (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

Authorized COVID-19 vaccines

For COVID-19 vaccines given under an Emergency Use Authorization (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 the Food and Drug Administration 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.

Adverse event reporting procedures

- Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967.
- Anyone can register in V-safe after their COVID-19 vaccination to receive health check-ins via text messages or email.

Clinical Considerations for Special Situations and Populations

AT A GLANCE

- Additional considerations may apply to people with prior SARS-CoV-2 infection, a history of multisystem inflammatory syndrome, or people who were vaccinated outside the United States.
- COVID-19 vaccination is recommended for women who are pregnant, trying to get pregnant, might become pregnant in the future, and who are breastfeeding.

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.

Pregnancy, lactation, and fertility

COVID-19 vaccination is recommended for women who are pregnant, trying to get pregnant, might become pregnant in the future, and 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 women, similar to those among non-pregnant women. Acetaminophen can be offered as an option for fever during pregnancy (fever has been associated with adverse pregnancy outcomes) or other post-vaccination symptoms.

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

Multisystem inflammatory syndrome in children (MIS-C) and multisystem inflammatory syndrome in adults (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 multisystem inflammatory syndrome (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 the section immediately above.

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

For persons in this category who meet the recovery criteria described in the section immediately above, 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.

People who received COVID-19 vaccine outside the United States

Everyone ages 6 months and older vaccinated outside the United States should receive at least 1 dose of 2024–2025 COVID-19 vaccine regardless of past COVID-19 vaccination history (e.g., vaccine type[s], vaccine manufacturer[s], number of doses) unless they received a 2024–2025 COVID-19 vaccine that is Food and Drug Administration (FDA)-approved or FDA-authorized (i.e., Moderna, Novavax, or Pfizer-BioNTech), or prequalified or listed for emergency use by the World Health Organization (WHO). COVID-19 vaccines that are pre-qualified or listed for emergency use by WHO, but are not approved or authorized by FDA, have not been evaluated for efficacy or safety by CDC or the Advisory Committee on Immunization Practices (ACIP).

Recommendations for people who were vaccinated outside the United States, but have not received a 2024–2025 COVID-19 vaccine are as follows:

People ages 5 years and older

- Previously received doses of COVID-19 vaccines that are FDA-approved, FDA-authorized or pre-qualified or listed for emergency use by WHO: Administer 1 age-appropriate dose of a 2024–2025 COVID-19 vaccine at least 8 weeks after the last COVID-19 vaccine dose (Table 1). **NOTE:** People ages 65 years and older should receive 2 doses of any 2024–2025 COVID-19 vaccine (Table 1).
- Previously received doses of COVID-19 vaccines that are **not** FDA-approved, FDA-authorized, or prequalified or listed for emergency use by WHO: The doses do not count towards vaccination in the United States and these people are considered unvaccinated; initiate vaccination at least 8 weeks after the last COVID-19 vaccine dose (Table 1).

Children ages 6 months–4 years and people who are moderately or severely immunocompromised

- Previously received doses of COVID-19 vaccines that are FDA-approved, FDA-authorized, or prequalified or listed for emergency use by WHO: The doses count towards vaccination in the United States; administer the number of age-appropriate doses of a 2024–2025 COVID-19 vaccine based on the schedule in Table 1 or Table 2.
- Previously received doses of COVID-19 vaccines that are **not** FDA-approved, FDA-authorized, or prequalified or listed for emergency use by WHO: The doses do not count towards vaccination in the United States and these people are considered unvaccinated; initiate vaccination at least 8 weeks after the last COVID-19 vaccine dose Table 1 or Table 2.

Special situation: If unable to determine if a previously received vaccine dose was a 2024–2025 COVID-19 vaccine, do not count the dose and follow guidance for administering a 2024–2025 COVID-19 vaccine dose.

Appendix: Vaccine Administration Errors and Deviations

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- Providers should consult the table on this page for guidance in managing different types of COVID-19 vaccine administration errors and deviations.
- Resources are provided for proper vaccine administration and error prevention.

Managing vaccine administration errors and deviations

NOTE
The package insert or Emergency Use Authorization (EUA) fact sheet for healthcare providers and U.S. COVID-19 Vaccine Product Information should be referenced for detailed information on storage and handling, dosing and schedule, dose preparation, and administration of COVID-19 vaccines. The information provided below on managing vaccine administration errors should not be interpreted as a recommendation or promotion of unauthorized use of the vaccines.

For all vaccine administration errors:

- Inform the recipient of the vaccine administration error.
- Consult with the jurisdiction immunization program and/or immunization information system (IIS) to determine how the dose should be entered into the IIS.
- Determine how the error occurred and implement strategies to prevent it from happening again. A discussion on strategies to prevent errors can be found in *Epidemiology and Prevention of Vaccine-Preventable Diseases* (Pink Book). Additional resources can be found on CDC's vaccine administration web page, including a job aid for preventing errors.
- Follow the revaccination guidance in the table below, using an age-appropriate COVID-19 vaccine product. Then continue with the recommended schedule for subsequent dose(s) unless otherwise noted in the table.

Vaccinators should consult Reporting of vaccine adverse events for information on reporting to the Vaccine Adverse Event Reporting System (VAERS) after COVID-19 vaccination. To file an electronic report, see the VAERS website.

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

Type	Administration error/deviation	Interim recommendation
Site/route	• Incorrect site (i.e., site other than the deltoid muscle or vastus lateralis muscle)	• Do not repeat dose.
	• Incorrect route (e.g., subcutaneous)	• Do not repeat dose. • Inform the recipient of the potential for local and systemic adverse events.
Age	• 2024–2025 mRNA vaccine administered to an unauthorized age group (recipients younger than age 6 months)	• If the first dose is administered 5 or more days before age 6 months, repeat the dose on or after the date the recipient reaches 6 months; space the repeat dose at least 4 weeks after the invalid dose.*
	• 2024–2025 Novavax vaccine administered to an unauthorized age group (recipients ages 6 months–11 years)	• If part of a multidose initial vaccination series (i.e., children ages 6 months–4 years or ages 6 months–11 years who are moderately or severely immunocompromised), count the dose; complete the initial series with a 2024–2025 mRNA vaccine; and space the next dose by at least the minimum interval (Table 1 and Table 2).† ○ For children ages 6 months–11 years who are moderately or severely immunocompromised, after completion of the initial series, administer 1 dose of any 2024–2025 mRNA vaccine 6 months (minimum interval 2 months) later; additional

Type	Administration error/deviation	Interim recommendation

		doses may be administered (Table 2).
		• For routine vaccination of children ages 5–11 years:
		  ○ If previously received 1 or more doses of any mRNA vaccine, no further doses are needed.
		  ○ If did not previously receive any doses of any mRNA vaccine, administer 1 dose of a 2024–2025 mRNA vaccine at least 4 weeks after the dose given in error.†

Product and dosage	• Higher-than-authorized dose administered (e.g., incorrect dose volume, incorrect product resulting in higher-than-authorized dose)	• Do not repeat dose.‡
	• Lower-than-authorized dose administered (e.g., leaked out of the syringe, equipment failure, recipient pulled away, incorrect product resulting in lower-than-authorized dose)	• Repeat dose immediately (no minimum interval).† • However, if a half-volume dose of vaccine is administered to a recipient recommended for the full volume, another half-volume dose can be administered on the same clinic day, and the 2 doses can count as 1 full dose.
Storage and handling	• Dose administered after improper storage and handling (i.e., temperature excursion)	• Contact the manufacturer for information on the stability of the vaccine.§ If the manufacturer does not have data to support the stability of

Type	Administration error/deviation	Interim recommendation
		the vaccine, repeat the dose immediately (no minimum interval).†
	• Dose administered past the expiration/beyond-use date	• Repeat the dose immediately (no minimum interval).†
Intervals	• Any COVID-19 dose administered prior to the minimum interval¶	• Repeat dose. Space the repeat dose after the dose given in error by at least the minimum interval (Table 1 and Table 2).†
Interchangeability#	• mRNA vaccines from different manufacturers administered as part of an initial vaccination series	• See Interchangeability of COVID-19 vaccines for detailed guidance on completion of vaccination when doses from different manufacturers are used. • If a previously completed 3-dose mRNA series did NOT include at least 1 dose of a 2024–2025 mRNA vaccine: ○ For routine vaccination of children ages 6 months–4 years, administer 1 dose of a 2024–2025 mRNA vaccine at least 8 weeks after the last dose (Table 1). ○ For people ages 6 months and older who are moderately or severely immunocompromised, administer 1 dose of an age-appropriate 2024–2025 COVID-19 vaccine at least 8 weeks after the last dose followed by a second dose of 2024–2025 vaccine 6 months (minimum interval 2 months) later; additional doses may be administered (Table 2).

Type	Administration error/deviation	Interim recommendation
	• One dose of 2024–2025 mRNA vaccine and 1 dose of 2024–2025 Novavax vaccine (in any order) administered to previously unvaccinated recipient age 12 years and older	• For routine vaccination of people ages 12–64 years, no further doses needed. • For routine vaccination of people ages 65 years and older, administer 1 dose of any 2024–2025 vaccine 6 months (minimum interval 2 months) after the last dose. • For people who are moderately or severely immunocompromised, administer 1 dose of any 2024–2025 vaccine at least 4 weeks after the last dose to complete initial vaccination, followed by 1 dose of any 2024–2025 vaccine 6 months (minimum interval 2 months) later; additional doses may be administered (Table 2).
Diluent (2024–2025 Pfizer-BioNTech COVID-19 Vaccine formulation that should be mixed with diluent)	• ONLY diluent administered (i.e., sterile 0.9% sodium chloride)	• Administer the authorized dose immediately (no minimum interval).
	• No diluent, resulting in higher than authorized dose	• Do not repeat dose. Inform the recipient of the potential for local and systemic adverse events.‡
	• Incorrect diluent type (e.g., sterile water, bacteriostatic 0.9% sodium chloride)	• Repeat the dose immediately (no minimum interval).†
	• Vaccine is mixed with too little diluent	• Do not repeat dose. Inform the recipient of the potential for local and systemic adverse events.‡
	• Vaccine is mixed with too much diluent	• Repeat dose immediately (no minimum interval).†
	• Single-use vial of diluent is used to mix	• Do not repeat dose. • See General Best Practice Guidelines for information on

Type	Administration error/deviation	Interim recommendation
	multiple vials of vaccine	infection control and sterile technique.
Diluent (2024–2025 Pfizer-BioNTech COVID-19 Vaccine formulations that should not be mixed with diluent)	• Vaccine is mixed with any diluent (i.e., any type or volume of diluent)	• Repeat the dose immediately (no minimum interval).[†]

*In addition to the minimum age, for children who are not moderately or severely immunocompromised, an 8-week interval between the invalid dose and the repeat dose might be optimal for some people as it might reduce the rare risk of myocarditis and pericarditis associated with mRNA (Moderna or Pfizer-BioNTech) COVID-19 vaccines and the potential for increased reactogenicity.

[†]For people ages 6 months–64 years who are not moderately or severely immunocompromised, an 8-week interval between the dose given in error and the repeat dose might be optimal for some people as it might reduce the rare risk of myocarditis and pericarditis associated with Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines, particularly in males ages 12–39 years, and the potential for increased reactogenicity.

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

[§]As of the date of this update, current manufacturer contact information is:
- Pfizer-BioNTech: 1-877-VAX-CO19 (1-877-829-2619)
- Moderna: 1-866-MODERNA (1-866-663-3762)
- Novavax: 1-844-NOVAVAX (1-844-668-2829)
See the package inserts and EUA fact sheets for the most up-to-date manufacturer information.

[¶]Vaccine doses administered up to 4 days before the minimum interval (i.e., grace period) may be counted and do not need to be repeated.

[#]See Interchangeability of COVID-19 vaccines for circumstances in which a COVID-19 vaccine from a different manufacturer may be administered; a VAERS report is not required in these circumstances.

References and Previous Updates

AT A GLANCE

- Key references are listed.
- Summaries of previous updates to the clinical considerations are listed chronologically.

Key References

- ACIP COVID-19 Vaccine Recommendations | CDC
- COVID-19 Vaccines | FDA
- COVID-19 Vaccine Emergency Use Instructions (EUI) Resources | CDC
- General Best Practices for Immunization

Previous updates

2024

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

September 6, 2024

- Recommendations for the use of 2024–2025 Novavax COVID-19 Vaccine in people ages 12 years and older
- Updated guidance in the Interchangeability of COVID-19 vaccines section and in Appendix B on completion of an initial vaccination series if vaccine doses from different manufacturers are administered in certain circumstances

August 23, 2024

Recommendations for 2024–2025 Moderna COVID-19 Vaccine and 2024–2025 Pfizer-BioNTech COVID-19 Vaccine

People who are not moderately or severely immunocompromised

Initial vaccination

- Ages 6 months–4 years
    - 2 doses of 2024–2025 Moderna or 3 doses of 2024–2025 Pfizer-BioNTech
- Ages 5 years and older
    - 1 dose of 2024–2025 Moderna or 1 dose of 2024–2025 Pfizer-BioNTech

Received previous doses of a COVID-19 vaccine

- Ages 6 months–4 years
    - 1 or 2 doses of 2024–2025 mRNA vaccine from the same manufacturer as administered for initial vaccination, depending on the vaccine and the number of prior doses
- Ages 5 years and older
    - 1 dose of 2024–2025 Moderna or 1 dose of 2024–2025 Pfizer-BioNTech

Additional dose: An additional dose of 2024–2025 COVID-19 vaccine for people ages 65 years and older who are not moderately or severely immunocompromised is NOT currently recommended.

People who are moderately or severely immunocompromised

Initial vaccination

- Ages 6 months and older
    - 3 doses of 2024–2025 Moderna or 3 doses of 2024–2025 Pfizer-BioNTech

Received previous doses of a COVID-19 vaccine

- Recommended mRNA vaccine and number of 2024–2025 doses are based on age and vaccination history

Additional doses: People who are moderately or severely immunocompromised ages 6 months and older may receive 1 or more age-appropriate doses of a 2024–2025 mRNA COVID-19 vaccine.

April 4, 2024

- New guidance on COVID-19 vaccination and pemivibart (Pemgarda™), a monoclonal antibody authorized for COVID-19 pre-exposure prophylaxis in people who are moderately or severely immunocompromised and meet the FDA-authorized conditions for use

March 1, 2024

- All people ages 65 years and older should receive 1 additional dose of any updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech). For detailed guidance, see Table 1 and Table 2.
- Updated information for reporting adverse events to VAERS following administration of a COVID-19 vaccine.

February 12, 2024

- Post-vaccination reaction information updated in sections on pre-vaccination counseling and safety considerations for mRNA and Novavax vaccines to better align with EUA fact sheets for healthcare providers and package inserts.
- Information on the availability of the V-safe safety monitoring system for updated (2023–2024 Formula) Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines added to the section on reporting of vaccine adverse events.

January 18, 2024

- Updated guidance on COVID-19 vaccine administration errors and deviations (Appendix B)

2023

November 3, 2023

- Guidance added to COVID-19 vaccination schedules for correct dosage and administration of updated (2023–2024 Formula) Moderna COVID-19 Vaccine in children ages 6 months–11 years.

October 24, 2023

- Age transitions: Updated guidance for children who transition during the initial COVID-19 vaccination series 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 to receive the age-appropriate dosage based on their age on the day of vaccination.
- Interchangeability of COVID-19 vaccines: Clarification of circumstances in which administration of COVID-19 vaccine doses from different manufacturers may be considered when doses from the same manufacturer are recommended.

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.

September 15, 2023

- Recommendations for use of the 2023–2024 formulations of Moderna COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine:
    - Everyone ages 5 years and older is recommended to receive 1 dose of updated (2023–-2024 Formula) mRNA COVID-19 vaccine
    - Children ages 6 months–4 years
        - Initial vaccination: should receive either 2 doses of updated (2023–2024 Formula) Moderna or 3 doses of updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 vaccine
        - Received previous mRNA doses: need 1 or 2 doses of updated (2023–2024 Formula) Moderna or updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 vaccine, depending on the number of prior doses
    - People who are moderately or severely immunocompromised
        - Initial vaccination: should receive a 3-dose series of updated (2023–2024 Formula) Moderna or updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 vaccine
        - Received previous mRNA doses: need 1 or 2 doses of updated (2023–2024 Formula) Moderna or updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 vaccine, depending on the number of prior doses
        - May receive 1 or more additional updated (2023–2024 Formula) mRNA COVID-19 vaccine doses
    - Bivalent mRNA COVID-19 vaccines are no longer recommended in the United States
- Updated guidance for COVID-19 vaccination and myocarditis or pericarditis

- Updated guidance for COVID-19 vaccination and Multisystem Inflammatory Syndrome (MIS) in children (MIS-C) and in adults (MIS-A)
- Reorganization and consolidation of sections on contraindications and precautions, including allergic reactions to COVID-19 vaccines

May 12, 2023

- Guidance for use of Janssen COVID-19 Vaccine has been removed as the vaccine is no longer available in the United States

May 1, 2023

- Revision of the mRNA COVID-19 vaccination schedule for people who are moderately or severely immunocompromised as follows:
    - At the time of initial vaccination, people ages 6 months and older are recommended to receive 3 bivalent mRNA doses
    - People ages 6 months and older who previously received only monovalent doses are recommended to receive 1 or 2 bivalent mRNA vaccine doses, depending on age and vaccine product
    - People who previously received a bivalent mRNA vaccine dose(s) have the option to receive 1 or more additional bivalent mRNA doses

April 22, 2023

- Revision of the mRNA COVID-19 vaccination schedule as follows:
    - At the time of initial vaccination, depending on vaccine product, children ages 6 months–4 years are recommended to receive 2 or 3 bivalent mRNA vaccine doses; children age 5 years are recommended to receive 1 or 2 bivalent mRNA vaccine doses
    - People ages 6 years and older who are unvaccinated or previously received only monovalent vaccine doses are recommended to receive 1 bivalent mRNA vaccine dose
    - People ages 65 years and older may receive 1 additional bivalent mRNA vaccine dose

March 16, 2023

- New recommendation for children ages 6 months–4 years who previously completed a 3-dose monovalent Pfizer-BioNTech primary series to receive 1 bivalent Pfizer-BioNTech booster dose at least 2 months after completion of the monovalent primary series.

- Vaccination providers are now required to report cases of myocarditis and pericarditis after receipt of a Janssen COVID-19 Vaccine to the Vaccine Adverse Event Reporting System (VAERS).

January 27, 2023

- As of January 26, 2023, EVUSHELD™ is not currently authorized for SARS-CoV-2 pre-exposure prophylaxis in the United States.

2022

December 9, 2022

- New recommendation for children ages 6 months–4 years who complete a Moderna primary series to receive 1 bivalent Moderna booster dose at least 2 months after completion of the primary series.
- Children age 5 years who complete a Moderna primary series may receive either the previously authorized bivalent Pfizer-BioNTech booster dose or the newly authorized bivalent Moderna booster dose at least 2 months after completion of the Moderna primary series.
- The previously authorized 3-dose Pfizer-BioNTech primary series for children ages 6 months–4 years has been revised as follows: a monovalent Pfizer-BioNTech vaccine is administered for the first and second doses, followed by 1 bivalent Pfizer-BioNTech vaccine as the third primary series dose, at least 8 weeks after the second monovalent primary series dose. A booster dose is not authorized for children in this age group who receive a Pfizer-BioNTech 3-dose primary series, including children who previously received a 3-dose monovalent Pfizer-BioNTech primary series.

October 19, 2022

- Guidance for use of a monovalent Novavax COVID-19 booster dose in people ages 18 years and older in limited situations

October 12, 2022

- New COVID-19 booster recommendations for people ages 5 years and older to receive 1 bivalent mRNA booster after completion of a monovalent primary series or previously received monovalent booster dose(s); these recommendations replace all prior booster recommendations for this age group
    - Recommendations for use of a bivalent Moderna booster dose in people ages 6–17 years
    - Recommendations for use of a bivalent Pfizer-BioNTech booster dose in people ages 5–11 years

September 23, 2022

- Reorganization and consolidation of the Interim Clinical Considerations to enhance usability. COVID-19 vaccination schedules and guidance are unchanged.

September 2, 2022

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

August 22, 2022

- Guidance for primary series vaccination using Novavax COVID-19 Vaccine in adolescents ages 12–17 years
- Reorganization of Janssen COVID-19 Vaccine guidance into an appendix

August 11, 2022

- Updated guidance on COVID-19 vaccination following exposure to SARS-CoV-2

July 20, 2022

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

June 30, 2022

- New clinical considerations for coadministration of mRNA COVID-19 vaccines and orthopoxvirus vaccines

June 24, 2022

- New guidance for use of Moderna COVID-19 Vaccine in children and adolescents ages 6–17 years

June 19, 2022

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

May 20, 2022

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

April 21, 2022

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

March 30, 2022

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

February 22, 2022

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

February 11, 2022

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

January 6, 2022

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

2021

December 23, 2021

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

December 17, 2021

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

December 10, 2021

- Updated guidance for use of Pfizer-BioNTech COVID-19 vaccine as a booster dose in persons aged 16 years and older

November 29, 2021

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

November 19, 2021

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

November 17, 2021

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

November 3, 2021

- Recommendations and clinical guidance for use of Pfizer-BioNTech COVID-19 Vaccine in children aged 5-11 years including updated section on Vaccination of children and adolescents
- Updated guidance on COVID-19 vaccine dosing and schedule
- Updated guidance for myocarditis and pericarditis after mRNA COVID-19 vaccination in new section on Considerations for mRNA COVID-19 vaccines: Pfizer-BioNTech and Moderna
- New guidance for people who received passive antibody products in section on COVID-19 vaccination and SARS-CoV-2 infection
- Updated guidance in section on People who received COVID-19 vaccine outside the United States
- Updated guidance in section on People who received COVID-19 as part of a clinical trial in the United States
- Updated guidance on Considerations for COVID-19 vaccination in moderately and severely immunocompromised people
- Updated guidance in section on Contraindications and precautions
- Updated Table in Appendix A: Vaccine administration errors and deviations
- Updated Appendix B: Triage of people with a history of allergies or allergic reactions
- Updated Appendix C: Ingredients included in COVID-19 vaccines

- Updated Appendix D: Potential characteristics of allergic reactions, vasovagal reactions, and vaccine side effects following COVID-19 vaccination

October 25, 2021

- Updated guidance in section on Considerations for use of a COVID-19 booster dose.
- New section added on Overview of COVID-19 vaccines recommendations.
- Updated guidance in section on COVID-19 vaccine dosage and schedule.
- Updated guidance in section on People vaccinated for prevention of COVID-19 outside the United States.
- Updated guidance in section on COVID-19 vaccination and SARS-CoV-2 infection for People with prior or current SARS-CoV-2 infection; People with a history of multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A); People who received passive antibody products; and Vaccinated people who subsequently develop COVID-19.
- New guidance on Considerations for COVID-19 revaccination in the section on Considerations for COVID-19 vaccination in moderately and severely immunocompromised people.
- Updated Table in Appendix A: Vaccine administration errors and deviations.

September 27, 2021

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

September 15, 2021

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

August 31, 2021

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

- Updated laboratory testing information on timing of immune-based tests for tuberculosis infection in relation to COVID-19 vaccine administration.

August 25, 2021

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

August 13, 2021

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

August 11, 2021

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

August 6, 2021

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

July 16, 2021

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

July 2, 2021

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

June 1, 2021

- Information on cases of myocarditis and pericarditis occurring after mRNA COVID-19 vaccination, particularly in adolescents and young adults.
- Information on the efficacy of the Pfizer-BioNTech COVID-19 Vaccine in adolescents aged 12–15 years in patient counseling section.

- Updated data on local and systemic symptoms following vaccination with mRNA COVID-19 vaccines in patient counseling section.
- Clarification in contraindications and precautions and Appendix B of guidance for people with a history of an immediate allergic reaction to a vaccine or injectable therapy that contains a component also contained in a COVID-19 vaccine.
- Updated list of ingredients in COVID-19 vaccines (i.e., lack of metals) in Appendix C.
- Correction of footnote numbering.

May 14, 2021

- Updated information for authorized age groups to include vaccination of adolescents aged 12–15 years with Pfizer-BioNTech COVID-19 Vaccine.
- Updated information on coadministration of COVID-19 vaccines with other vaccines.
- A new section on persons with a history of multisystem inflammatory syndrome added to considerations for vaccination of people with certain underlying medical conditions.
- Updated recommendation for timing of COVID-19 vaccine administration in persons with a history of heparin-induced thrombocytopenia.
- Updated information on vaccination of children and adolescents.

April 27, 2021

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

- New section added on considerations for use of the Janssen COVID-19 Vaccine in certain populations.
- Updated information and recommendations for vaccination of women who are pregnant or lactating.
- Updated recommendations for vaccination of children and adolescents.
- Updated information related to axillary lymphadenopathy added to patient counseling for mRNA COVID-19 vaccines.
- Updated information on the Janssen COVID-19 Vaccine added to patient counseling.
- Updated recommendations related to contraindications (polysorbate allergy) and precautions (most people with a precaution can and should be administered vaccine) for COVID-19 vaccines.

April 16, 2021

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

March 5, 2021

- Public health recommendations for vaccinated people have been moved to: www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.

March 3, 2021

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

February 10, 2021

- New recommendations for preventing, reporting, and managing mRNA COVID-19 vaccine administration errors (Appendix A).
- Clarification on contraindications and precautions. People with a known (diagnosed) allergy to PEG, another mRNA vaccine component, or polysorbate, have a contraindication to vaccination. People with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is PEG, another mRNA vaccine component or polysorbate, but in

whom it is unknown which component elicited the immediate allergic reaction have a precaution to vaccination.

- Updated information on delayed, local injection-site reactions after the first mRNA vaccine dose. These reactions are neither a contraindication nor a precaution to the second dose.
- Updated quarantine recommendations for vaccinated people. Fully vaccinated people who meet criteria will no longer be required to quarantine following an exposure to someone with COVID-19. Additional considerations for patients and residents in healthcare settings are provided.
- Additional information and updated recommendations for testing for TB infection. TB testing can be done before or at the same time as mRNA COVID-19 vaccination, or otherwise delayed for ≥4 weeks after the completion of mRNA COVID-19 vaccination.