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

AT A GLANCE

- These clinical considerations provide guidance to 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 November 4, 2025

- The COVID-19 vaccination recommendations have been updated to reflect individual-based decision-making (also known as shared clinical decision-making) for people ages 6 months and older.
- Pfizer-BioNTech COVID-19 Vaccine is no longer authorized for children ages 6 months–4 years. The only FDA-approved COVID-19 vaccine available for this age group is Moderna (Spikevax).

Get email updates

Sign up for our email newsletter

Implementation resources

- General Immunization Schedules (Updated 10/7/2025)

Overview of COVID-19 Vaccines and Vaccination

AT A GLANCE

- 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).
- Vaccination is based on individual-based decision-making (also known as shared clinical decision-making).
- Schedules for the 2025–2026 COVID-19 vaccines are based on age and immune status.

Introduction

These clinical considerations provide guidance 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 by the U.S. Food and Drug Administration (FDA)
- General Best Practices for Immunization

Types of COVID-19 vaccines

Two types of 2025–2026 COVID-19 vaccines are recommended for use in the United States:

- mRNA vaccines
  - Moderna COVID-19 Vaccines: Spikevax (approved for ages 6 months and older) and mNexspike (approved for ages 12 years and older). These vaccines are hereafter referred to collectively as Moderna COVID-19 Vaccine unless the specific vaccine name is relevant.
  - Pfizer-BioNTech COVID-19 Vaccine: Comirnaty (approved for ages 5 years and older). This vaccine is hereafter referred to as Pfizer-BioNTech COVID-19 Vaccine. There is currently no FDA-approved or FDA-authorized Pfizer-BioNTech COVID-19 vaccine for ages 6 months–4 years.

- Protein subunit vaccine
    - Novavax COVID-19 Vaccine: Nuvaxovid (approved for ages 12 years and older). This vaccine is hereafter referred to as Novavax COVID-19 Vaccine.

Age groups for approved use of 2025–2026 COVID-19 vaccines

- **Moderna (Spikevax):** 6 months and older
- **Moderna (mNexspike):** 12 years and older
- **Pfizer-BioNTech (Comirnaty):** 5 years and older
- **Novavax (Nuvaxovid):** 12 years and older

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.

The 2024–2025 Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines should not be used.

COVID-19 vaccine composition

The 2025–2026 formulations for COVID-19 vaccines in the United States are based on the Omicron JN.1-lineage of SARS-CoV-2, as follows:

- Moderna and Pfizer-BioNTech: LP.8.1 strain
- Novavax: JN.1 strain

COVID-19 vaccine-specific package inserts 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.

Overview of recommendations for the use of COVID-19 vaccines

Groups recommended for vaccination

COVID-19 vaccination is recommended for the prevention of COVID-19 disease and its complications as follows:

- **Adults ages 65 years and older:** Vaccination based on individual-based decision-making (also known as shared clinical decision-making)
- **People ages 6 months–64 years:** Vaccination based on individual-based decision-making (also known as shared clinical decision-making)—with an emphasis that the risk-benefit of vaccination is most favorable for individuals who are at an increased risk for severe COVID-19 disease and lowest for individuals who are not at an increased risk, according to the CDC list of COVID-19 risk factors.

In addition to the CDC list of risk factors for severe COVID-19, the Moderna (Spikevax) package insert states that prematurity (birth at <37 weeks gestational age) has been associated with COVID-19-related hospitalizations in children ages 6–23 months.

Additionally, some people may be at increased risk for SARS-CoV-2 infection including healthcare workers and residents and employees in long-term care facilities and other residential congregate settings.

The vaccination schedules for the 2025–2026 COVID-19 vaccines vary based on vaccination history, age group, and immune status. Detailed schedules, including age-appropriate vaccines, dosages, and intervals between doses for the 2025–2026 COVID-19 vaccines can be found in Table 1; a modified schedule for people who are moderately or severely immunocompromised can be found in Table 2. Because there is no current FDA-approved or FDA-authorized Pfizer-BioNTech COVID-19 Vaccine for children ages 6 months–4 years, the 2025–2026 COVID-19 vaccination schedule has been modified to ensure children previously vaccinated with Pfizer-BioNTech COVID-19 Vaccine receive a 2025–2026 COVID-19 vaccine dose(s) with Moderna (Spikevax) COVID-19 Vaccine.

Self-attestation of COVID-19 risk factors

People can self-attest to factors that increase their risk for severe COVID-19 during the individual-based decision-making process 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.

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.

2025–2026 COVID-19 Vaccination Guidance

AT A GLANCE

- The 2025–2026 COVID-19 vaccine is recommended for people ages 6 months and older based on individual-based decision-making (also known as shared clinical decision making).
- The recommended vaccine and number of doses are based on age and vaccination history.
- People can self-attest to factors that increase their risk for severe COVID-19 and receive COVID-19 vaccination.
- See Table 2 for the vaccination schedule for people who are moderately or severely immunocompromised.

Introduction

COVID-19 vaccination is recommended for all adults ages 65 years and older based on individual-based decision-making (also known as shared clinical decision-making). For people ages 6 months–64 years, vaccination is recommended based on individual-based decision-making (also known as shared clinical decision-making)—with an emphasis that the risk-benefit of vaccination is most favorable for individuals who are at an increased risk for severe COVID-19 disease and lowest for individuals who are not at an increased risk, according to the CDC list of COVID-19 risk factors. In addition to the CDC list, the Moderna (Spikevax) package insert states that prematurity (birth at <37 weeks gestational age) has been associated with COVID-19-related hospitalizations in children ages 6–23 months.

Additionally, some people may be at increased risk for SARS-CoV-2 infection including healthcare workers and residents and employees in long-term care facilities and other residential congregate settings.

The 2025–2026 COVID-19 vaccination schedule is detailed in Table 1. The recommended vaccine and number of 2025–2026 COVID-19 vaccine doses are based on age and vaccination history.

Key updates to the 2025–2026 COVID-19 vaccination schedule

- For children ages 6 months–4 years, only Moderna (Spikevax) COVID-19 Vaccine is approved for use; Pfizer-BioNTech COVID-19 Vaccine is no longer authorized for this age group.
- Novavax COVID-19 Vaccine, approved for people ages 12 years and older, is administered as a single dose for initial vaccination.
- Moderna (mNexspike) COVID-19 Vaccine is approved for people ages 12 years and older.

Table 1: 2025–2026 COVID-19 vaccination schedule, November 4, 2025

1a: Ages 6–23 months

NOTE

In Table 1a, Moderna refers to Spikevax, the only COVID-19 vaccine approved for this age group.

Children ages 6–23 months previously vaccinated with Pfizer-BioNTech COVID-19 Vaccine should receive dose(s) of 2025–2026 Moderna COVID-19 Vaccine.

COVID-19 vaccination history before 2025–2026 vaccine*	Number of 2025–2026 doses indicated	Recommended 2025–2026 vaccine† and interval between doses
Unvaccinated: • Administer initial series with 2025–2026 vaccine		
Unvaccinated	2	**2025–2026 Dose 1** (Moderna): Day 0 **2025–2026 Dose 2** (Moderna): 4–8 weeks after 2025–2026 Dose 1‡
Initiated but did not complete the initial series before 2025–2026 vaccine: • Complete initial series with 2025–2026 vaccine		
1 dose Moderna	1	**2025–2026 Dose 1** (Moderna): 4–8 weeks after last dose‡
1 dose Pfizer-BioNTech	2	**2025–2026 Dose 1** (Moderna): 3–8 weeks after last dose‡ **2025–2026 Dose 2** (Moderna): At least 4 weeks after 2025–2026 Dose 1
2 doses Pfizer-BioNTech	1	**2025–2026 Dose 1** (Moderna): At least 8 weeks after last dose
Completed the initial series before 2025–2026 vaccine: • Administer 1 dose of 2025–2026 vaccine		
2 or more doses Moderna or 3 or more doses Pfizer-BioNTech	1	**2025–2026 Dose 1** (Moderna): 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 2025–2026 COVID-19 vaccines.

†Dosage for Moderna (Spikevax): 0.25 mL/25 ug.

‡An 8-week interval between the first and second COVID-19 vaccine doses (i.e., extended interval) might reduce the rare risk of myocarditis and pericarditis associated with COVID-19 vaccines.

1b: Ages 2–4 years

NOTE

In Table 1b, Moderna refers to Spikevax, the only COVID-19 vaccine approved for this age group.

Moderna (Spikevax) is now administered to this age group as a single dose regardless of COVID-19 vaccination history.

See footnote* for guidance on children who transition from age 23 months to 2 years during initial vaccination with 2025–2026 vaccine.

COVID-19 vaccination history before 2025–2026 vaccine†	Number of 2025–2026 doses indicated	Recommended 2025–2026 vaccine‡ and interval between doses
Unvaccinated: • Administer initial vaccination with 2025–2026 vaccine		
Unvaccinated	1	**2025–2026 Dose 1** (Moderna): Day 0
Previously vaccinated before 2025–2026 vaccine: • Administer 1 dose of 2025–2026 vaccine		
1 or more doses mRNA (Moderna or Pfizer-BioNTech) vaccine	1	**2025–2026 Dose 1** (Moderna): At least 8 weeks after last dose

*Children who transition from age 23 months to age 2 years during the initial vaccination with 2025–2026 vaccine (i.e., after they received Dose 1 but before Dose 2) should receive 1 dose of Moderna (Spikevax) 4–8 weeks after Dose 1.

†COVID-19 vaccination history refers to all doses of COVID-19 vaccine from any manufacturer received before the availability of the 2025–2026 COVID-19 vaccines.

‡Dosage for Moderna (Spikevax): 0.25 mL/25 ug.

1c: Ages 5–11 years

NOTE

Moderna (Spikevax) and Pfizer-BioNTech COVID-19 vaccines are approved for use in this age group.

In Table 1c, Moderna refers to Spikevax.

COVID-19 vaccination history before 2025–2026 vaccine*	Number of 2025–2026 doses indicated	Recommended 2025–2026 vaccine† and interval between doses
Unvaccinated: • Administer 1 dose of 2025–2026 vaccine		
Unvaccinated	1	**2025–2026 Dose 1** (Moderna or Pfizer-BioNTech): Day 0
Previously vaccinated before 2025–2026 vaccine: • Administer 1 dose of 2025–2026 vaccine		
1 or more doses mRNA (Moderna or Pfizer-BioNTech) vaccine	1	**2025–2026 Dose 1** (Moderna 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 2025–2026 COVID-19 vaccines.

†Dosage for Moderna (Spikevax): 0.25 mL/25 ug; dosage for Pfizer-BioNTech: 0.3 mL/10 ug.

1d: Ages 12–64 years

NOTE

Moderna (mNexspike), Moderna (Spikevax), Novavax, and Pfizer-BioNTech COVID-19 vaccines are approved for this age group.

Novavax is administered as a single dose for initial vaccination.

COVID-19 vaccination history before 2025–2026 vaccine*	Number of 2025–2026 doses indicated	Recommended 2025–2026 vaccine† and interval between doses
Unvaccinated: • Administer 1 dose of 2025–2026 vaccine		
Unvaccinated	1	**2025–2026 Dose 1** (Moderna, Novavax, or Pfizer-BioNTech): Day 0
Previously vaccinated before 2025–2026 vaccine: • Administer 1 dose of 2025–2026 vaccine		
1 or more doses any COVID-19 vaccine (Moderna, Novavax, or Pfizer-BioNTech)	1	**2025–2026 Dose 1** (Moderna [Spikevax], Novavax, or Pfizer-BioNTech): At least 8 weeks after last dose; (Moderna [mNexspike]): At least 3 months after last dose‡

*COVID-19 vaccination history refers to all doses of COVID-19 vaccine from any manufacturer received before the availability of the 2025–2026 COVID-19 vaccines.

[†]Dosage for Moderna (mNexspike): 0.2 mL/10 ug; dosage for Moderna (Spikevax): 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.

[‡]The recommended interval for Moderna (mNexspike) is 3 months after the last dose; however, a dose administered at least 2 months after the last dose should not be repeated.

1e: Ages 65 years and older

NOTE

Moderna (mNexspike), Moderna (Spikevax), Novavax, and Pfizer-BioNTech COVID-19 vaccines are approved for this age group.

COVID-19 vaccination history before 2025–2026 vaccine[*]	Number of 2025–2026 doses indicated	Recommended 2025–2026 vaccine[†] and interval between doses
Unvaccinated: • Administer 2 doses of 2025–2026 vaccine		
Unvaccinated	2	**2025–2026 Dose 1** (Moderna, Novavax, or Pfizer-BioNTech): Day 0 **2025–2026 Dose 2** (Moderna [Spikevax], Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2025–2026 Dose 1; (Moderna [mNexspike]): 6 months (minimum interval 3 months)[‡] after 2025–2026 Dose 1
Previously vaccinated before 2025–2026 vaccine: • Administer 2 doses of 2025–2026 vaccine		

COVID-19 vaccination history before 2025–2026 vaccine*	Number of 2025–2026 doses indicated	Recommended 2025–2026 vaccine† and interval between doses
1 or more doses any COVID-19 vaccine (Moderna, Novavax, or Pfizer-BioNTech)	2	**2025–2026 Dose 1** (Moderna [Spikevax], Novavax, or Pfizer-BioNTech): At least 8 weeks after last dose; (Moderna [mNexspike]): At least 3 months after last dose‡ **2025–2026 Dose 2** (Moderna [Spikevax], Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2025–2026 Dose 1; (Moderna [mNexspike]): 6 months (minimum interval 3 months)‡ after 2025–2026 Dose 1

*COVID-19 vaccination history refers to all doses of COVID-19 vaccine from any manufacturer received before the availability of the 2025–2026 COVID-19 vaccines.

†Dosage for Moderna (mNexspike): 0.2 mL/10 ug; dosage for Moderna (Spikevax): 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.

‡The recommended interval for Moderna (mNexspike) is 3 months after the last dose; however, a dose administered at least 2 months after the last dose should not be repeated.

Self-attestation of COVID-19 risk factors

People can self-attest to factors that increase their risk for severe COVID-19 during the individual-based decision-making process 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.

COVID-19 Vaccination Guidance for People Who Are Immunocompromised

AT A GLANCE

- COVID-19 vaccination is recommended for people ages 6 months and older who are moderately or severely immunocompromised based on individual-based decision-making (also known as shared clinical decision making).
- There is a modified 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 vaccination.
- Administering COVID-19 vaccines should not be delayed in patients taking immunosuppressive therapies.

Introduction

COVID-19 vaccination is recommended for people ages 6 months and older based on individual-based decision-making (also known as shared clinical decision-making). Moderate or severe immunocompromise is a risk factor for severe COVID-19. The recommended vaccine and number of 2025–2026 COVID-19 vaccine doses for people who are moderately or severely immunocompromised are based on age and vaccination history (Table 2).

Key updates to the 2025–2026 COVID-19 vaccination schedule for people who are moderately or severely immunocompromised:

- For children ages 6 months–4 years, only Moderna (Spikevax) COVID-19 Vaccine is approved for use; Pfizer-BioNTech COVID-19 Vaccine is no longer authorized for this age group.
- Moderna (mNexspike) COVID-19 vaccine is approved for people ages 12 years and older.
- For the multidose initial series, some of the intervals have been revised.
- For people who have completed the multidose initial series, two doses of age-appropriate 2025–2026 COVID-19 vaccine are recommended; additional doses are no longer recommended.

Table 2: 2025–2026 COVID-19 vaccination schedule for people who are moderately or severely immunocompromised, November 4, 2025

2a: Ages 6 months–4 years

NOTE

In Table 2a, Moderna refers to Spikevax, the only COVID-19 vaccine approved for this age group.

Children previously vaccinated with Pfizer-BioNTech COVID-19 Vaccine should receive dose(s) of 2025–2026 Moderna COVID-19 Vaccine.

COVID-19 vaccination history before 2025–2026 vaccine*	Number of 2025–2026 doses indicated	Recommended 2025–2026 vaccine† and interval between doses
Unvaccinated: • Administer an initial 3-dose series with 2025–2026 vaccine • Administer 1 dose of 2025–2026 vaccine 6 months after completing initial series		
Unvaccinated	4	**2025–2026 Dose 1** (Moderna): Day 0 **2025–2026 Dose 2** (Moderna): 4 weeks after 2025–2026 Dose 1 **2025–2026 Dose 3** (Moderna): At least 4 weeks after 2025–2026 Dose 2 **2025–2026 Dose 4** (Moderna): 6 months (minimum interval 2 months) after 2025–2026 Dose 3

Initiated but did not complete the 3-dose initial series before 2025–2026 vaccine: • Complete the 3-dose series with 2025–2026 vaccine • Administer 1 dose of 2025–2026 vaccine 6 months after completing initial series		
1 dose Moderna	3	**2025–2026 Dose 1** (Moderna): 4 weeks after last dose **2025–2026 Dose 2** (Moderna): At least 4 weeks after 2025–2026 Dose 1 **2025–2026 Dose 3** (Moderna): 6 months (minimum interval 2 months) after 2025–2026 Dose 2
2 doses Moderna	2	**2025–2026 Dose 1** (Moderna): At least 4 weeks after last dose **2025–2026 Dose 2** (Moderna): 6 months (minimum interval 2 months) after 2025–2026 Dose 1
1 dose Pfizer-BioNTech	3	**2025–2026 Dose 1** (Moderna): 3 weeks after last dose **2025–2026 Dose 2** (Moderna): At least 4 weeks after 2025–2026 Dose 1 **2025–2026 Dose 3** (Moderna): 6 months (minimum interval 2 months) after 2025–2026 Dose 2
2 doses Pfizer-BioNTech	2	**2025–2026 Dose 1** (Moderna): At least 8 weeks after last dose **2025–2026 Dose 2** (Moderna): 6 months (minimum interval 2 months) after 2025–2026 Dose 1

Completed the 3-dose initial series before 2025–2026 vaccine: • Administer 2 doses of 2025–2026 vaccine spaced 6 months apart		
3 or more doses Moderna or 3 or more doses Pfizer-BioNTech	2	**2025–2026 Dose 1** (Moderna): At least 8 weeks after last dose **2025–2026 Dose 2** (Moderna): 6 months (minimum interval 2 months) after 2025–2026 Dose 1

*COVID-19 vaccination history refers to all doses of COVID-19 vaccine from any manufacturer received before the availability of the 2025–2026 COVID-19 vaccines.

†Dosage for Moderna (Spikevax): 0.25 mL/25 ug.

2b: Ages 5–11 years

NOTE

Moderna (Spikevax) and Pfizer-BioNTech vaccines are approved for this age group. In Table 2b, Moderna refers to Spikevax.

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 2025–2026 vaccine†	Number of 2025–2026 doses indicated	Recommended 2025–2026 vaccine‡ and interval between doses
Unvaccinated: • Administer an initial 3-dose series with 2025–2026 vaccine • Administer 1 dose of 2025–2026 vaccine 6 months after completing initial series		

<table>
<tr><th>COVID-19 vaccination history before 2025–2026 vaccine[†]</th><th>Number of 2025–2026 doses indicated</th><th>Recommended 2025–2026 vaccine[‡] and interval between doses</th></tr>
<tr><td rowspan="3">Unvaccinated</td><td>4</td><td>2025–2026 Dose 1 (Moderna): Day 0

2025–2026 Dose 2 (Moderna): 4 weeks after 2025–2026 Dose 1

2025–2026 Dose 3 (Moderna): At least 4 weeks after 2025–2026 Dose 2

2025–2026 Dose 4 (Moderna or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2025–2026 Dose 3</td></tr>
<tr><td colspan="2">OR</td></tr>
<tr><td>4</td><td>2025–2026 Dose 1 (Pfizer-BioNTech): Day 0

2025–2026 Dose 2 (Pfizer-BioNTech): 3 weeks after 2025–2026 Dose 1

2025–2026 Dose 3 (Pfizer-BioNTech): At least 4 weeks after 2025–2026 Dose 2

2025–2026 Dose 4 (Moderna or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2025–2026 Dose 3</td></tr>
<tr><td colspan="3">Initiated but did not complete the 3-dose initial series before 2025–2026 vaccine:

• Complete the 3-dose series with 2025–2026 vaccine
• Administer 1 dose of 2025–2026 vaccine 6 months after completing initial series</td></tr>
<tr><td>1 dose Moderna</td><td>3</td><td>2025–2026 Dose 1 (Moderna): 4 weeks after last dose</td></tr>
</table>

COVID-19 vaccination history before 2025–2026 vaccine[†]	Number of 2025–2026 doses indicated	Recommended 2025–2026 vaccine[‡] and interval between doses
		2025–2026 Dose 2 (Moderna): At least 4 weeks after 2025–2026 Dose 1 **2025–2026 Dose 3** (Moderna or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2025–2026 Dose 2
2 doses Moderna	2	**2025–2026 Dose 1** (Moderna): At least 4 weeks after last dose **2025–2026 Dose 2** (Moderna or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2025–2026 Dose 1
1 dose Pfizer-BioNTech	3	**2025–2026 Dose 1** (Pfizer-BioNTech): 3 weeks after last dose **2025–2026 Dose 2** (Pfizer-BioNTech): At least 4 weeks after 2025–2026 Dose 1 **2025–2026 Dose 3** (Moderna or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2025–2026 Dose 2
2 doses Pfizer-BioNTech	2	**2025–2026 Dose 1** (Pfizer-BioNTech): At least 4 weeks after last dose **2025–2026 Dose 2** (Moderna or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2025–2026 Dose 1
Completed the 3-dose initial series before 2025–2026 vaccine: • Administer 2 doses of 2025–2026 vaccine spaced 6 months apart		

COVID-19 vaccination history before 2025–2026 vaccine[†]	Number of 2025–2026 doses indicated	Recommended 2025–2026 vaccine[‡] and interval between doses
3 or more doses Moderna or 3 or more doses Pfizer-BioNTech	2	**2025–2026 Dose 1** (Moderna or Pfizer-BioNTech): At least 8 weeks after last dose **2025–2026 Dose 2** (Moderna or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2025–2026 Dose 1

[*]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: 2025–2026 Moderna, 0.25 mL/25 ug; there is no dosage change
- Pfizer-BioNTech series: 2025–2026 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 2025–2026 COVID-19 vaccines.

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

2c: Ages 12 years and older

NOTE

Moderna (mNexspike), Moderna (Spikevax), Novavax, and Pfizer-BioNTech COVID-19 vaccines are approved for this age group.

Moderna (mNexspike) and Moderna (Spikevax) may be used interchangeably in the initial 3-dose series.

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

<table>
<tr><th>COVID-19 vaccination history before 2025–2026[†]</th><th>Number of 2025–2026 doses indicated</th><th>Recommended 2025–2026 vaccine[‡] and interval between doses</th></tr>
<tr><td colspan="3">Unvaccinated:
Administer an initial series with 2025–2026 vaccine
Administer 1 dose of 2025–2026 vaccine 6 months after completing initial series</td></tr>
<tr><td rowspan="3">Unvaccinated</td><td>4</td><td>2025–2026 Dose 1 (Moderna): Day 0

2025–2026 Dose 2 (Moderna): 4 weeks after 2025–2026 Dose 1

2025–2026 Dose 3 (Moderna): At least 4 weeks after 2025–2026 Dose 2

2025–2026 Dose 4 (Moderna [Spikevax], Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2025–2026 Dose 3; (Moderna [mNexspike]): 6 months (minimum interval 3 months)[§] after 2025–2026 Dose 3</td></tr>
<tr><td colspan="2">OR</td></tr>
<tr><td>3</td><td>2025–2026 Dose 1 (Novavax): Day 0

2025–2026 Dose 2 (Novavax): 3 weeks after 2025–2026 Dose 1

2025–2026 Dose 3 (Moderna [Spikevax], Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2025–2026 Dose 2; (Moderna [mNexspike]): 6 months (minimum interval 3 months)[§] after 2025–2026 Dose 2</td></tr>
<tr><td colspan="2">OR</td></tr>
</table>

COVID-19 vaccination history before 2025–2026[†]	Number of 2025–2026 doses indicated	Recommended 2025–2026 vaccine[‡] and interval between doses
	4	**2025–2026 Dose 1** (Pfizer-BioNTech): Day 0 **2025–2026 Dose 2** (Pfizer-BioNTech): 3 weeks after 2025–2026 Dose 1 **2025–2026 Dose 3** (Pfizer-BioNTech): At least 4 weeks after 2025–2026 Dose 2 **2025–2026 Dose 4** (Moderna [Spikevax], Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2025–2026 Dose 3; (Moderna [mNexspike]): 6 months (minimum interval 3 months)[§] after 2025–2026 Dose 3
Initiated but did not complete the initial series before 2025–2026 vaccine: • Complete the initial series with 2025–2026 vaccine • Administer 1 dose of 2025–2026 vaccine 6 months after completing initial series		
1 dose Moderna	3	**2025–2026 Dose 1** (Moderna): 4 weeks after last dose **2025–2026 Dose 2** (Moderna): At least 4 weeks after 2025–2026 Dose 1 **2025–2026 Dose 3** (Moderna [Spikevax], Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2025–2026 Dose 2; (Moderna [mNexspike]): 6 months (minimum interval 3 months)[§] after 2025–2026 Dose 2
2 doses Moderna	2	**2025–2026 Dose 1** (Moderna): At least 4 weeks after last dose

COVID-19 vaccination history before 2025–2026[†]	Number of 2025–2026 doses indicated	Recommended 2025–2026 vaccine[‡] and interval between doses
		2025–2026 Dose 2 (Moderna [Spikevax], Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2025–2026 Dose 1; (Moderna [mNexspike]): 6 months (minimum interval 3 months)[§] after 2025–2026 Dose 1
1 dose Pfizer-BioNTech	3	**2025–2026 Dose 1** (Pfizer-BioNTech): 3 weeks after last dose **2025–2026 Dose 2** (Pfizer-BioNTech): At least 4 weeks after 2025–2026 Dose 1 **2025–2026 Dose 3** (Moderna [Spikevax], Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2025–2026 Dose 2; (Moderna [mNexspike]): 6 months (minimum interval 3 months)[§] after 2025–2026 Dose 2
2 doses Pfizer-BioNTech	2	**2025–2026 Dose 1** (Pfizer-BioNTech): At least 4 weeks after last dose **2025–2026 Dose 2** (Moderna [Spikevax], Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2025–2026 Dose 1; (Moderna [mNexspike]): 6 months (minimum interval 3 months)[§] after 2025–2026 Dose 1
1 dose Novavax	2	**2025–2026 Dose 1** (Novavax): At least 3 weeks after last dose

COVID-19 vaccination history before 2025–2026[†]	Number of 2025–2026 doses indicated	Recommended 2025–2026 vaccine[‡] and interval between doses
		2025–2026 Dose 2 (Moderna [Spikevax], Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2025–2026 Dose 1; (Moderna [mNexspike]): 6 months (minimum interval 3 months)[§] after 2025–2026 Dose 1
Completed the initial series before 2025–2026 vaccine: • Administer 2 doses of 2025–2026 vaccine spaced 6 months apart		
3 or more doses Moderna or 3 or more doses Pfizer-BioNTech	2	**2025–2026 Dose 1** (Moderna [Spikevax], Novavax, or Pfizer-BioNTech): At least 8 weeks after last dose; (Moderna [mNexspike]): At least 3 months after last dose[§] **2025–2026 Dose 2** (Moderna [Spikevax], Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2025–2026 Dose 1; (Moderna [mNexspike]): 6 months (minimum interval 3 months)[§] after 2025–2026 Dose 1
2 or more doses Novavax	2	**2025–2026 Dose 1** (Moderna [Spikevax], Novavax, or Pfizer-BioNTech): At least 8 weeks after last dose; (Moderna [mNexspike]): At least 3 months after last dose[§] **2025–2026 Dose 2** (Moderna [Spikevax], Novavax, or Pfizer-BioNTech): 6 months (minimum interval 2 months) after 2025–2026 Dose 1; (Moderna [mNexspike]): 6 months (minimum interval 3 months)[§] after 2025–2026 Dose 1

[*] 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.

[†] COVID-19 vaccination history refers to all doses of COVID-19 vaccine from any manufacturer received before the availability of the 2025–2026 COVID-19 vaccines.

[‡] Dosage for Moderna (mNexspike): 0.2 mL/10 ug; dosage for Moderna (Spikevax): 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.

[§] The recommended interval for Moderna (mNexspike) is 3 months after the last dose; however, a dose administered at least 2 months after the last dose should not be repeated.

Self-attestation of immunocompromised status

People can self-attest to their moderately or severely immunocompromised status during the individual-based decision-making process 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.

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.

Development of moderate or severe immunocompromise and revaccination

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 in Table 2.

Considerations for 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 for people who are unvaccinated (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.

Implementation Guidance

AT A GLANCE

- Implementation guidance addresses practical issues that may arise during COVID-19 vaccination including simultaneous administration and interchangeability.

Simultaneous administration of COVID-19 vaccines with other vaccines

Routine administration of all age-appropriate doses of vaccines simultaneously, also known as coadministration, is acceptable 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 in most scenarios 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 out of an abundance of caution. 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 and **Clesrovimab:** Simultaneous administration of COVID-19 vaccine and nirsevimab or clesrovimab (long-acting monoclonal antibodies indicated for certain infants and young children for prevention of respiratory syncytial virus [RSV] lower respiratory tract disease) is acceptable.

Interchangeability of COVID-19 vaccines

The same COVID-19 vaccine should be administered whenever recommended (Table 1 and Table 2). In the following circumstances, a different age-appropriate COVID-19 vaccine 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

Because there is no current FDA-approved or FDA-authorized Pfizer-BioNTech COVID-19 Vaccine for children ages 6 months–4 years, the 2025–2026 COVID-19 vaccination schedule has been modified to ensure children previously vaccinated with Pfizer-BioNTech COVID-19 Vaccine receive a 2025–2026 COVID-19 vaccine dose(s) with Moderna (Spikevax) COVID-19 Vaccine (Table 1 and Table 2).

A Vaccine Adverse Event Reporting System (VAERS) report is not indicated in any of the above circumstances.

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 before each vaccine dose 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.§

Medical condition or history	Guidance	Recommended action
History of a non-severe, immediate (onset less than 4 hours) allergic reaction* after administration of a previous dose of one COVID-19 vaccine type§	Precaution	For additional information, see Considerations for people with a 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

*For definitions of allergic reactions in Table 3 consult Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination.

†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 Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination.

‡See package inserts 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 healthcare provider experienced in the management of severe allergic reactions. Additionally, if the same vaccine type is administered, an observation period of 30 minutes post-vaccination to monitor for allergic reactions and 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.
- Reporting to the Vaccine Adverse Event Reporting System (VAERS) is strongly encouraged.
- Information on reporting adverse events to VAERS and how to register in V-safe is provided.

Safety considerations for COVID-19 vaccines

In clinical trials of COVID-19 vaccines, post-vaccination reactions were generally similar. While the frequency of some reactions varied by age, vaccine manufacturer, and vaccine dose, commonly reported reactions follow below.

- Local reactions included pain/tenderness, and, less commonly, swelling and redness at the injection site, and localized axillary or groin adenopathy on the same side as the vaccinated arm or thigh.
- Systemic reactions included fever, fatigue/malaise, headache, chills, myalgia, arthralgia, and diarrhea; among younger children, particularly those younger than age 3 years, systemic reactions also included irritability/crying, sleepiness, and loss of appetite.

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

Package inserts can be consulted for detailed information about post-vaccination reactions.

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 vaccine clinical trial; febrile seizures have been reported during postmarketing use of the vaccine. 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.

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. 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 also suggest an increased risk of myocarditis and pericarditis following Novavax vaccination.

Vaccine recipients, especially males ages 12–39 years, should be made aware of the rare risk of myocarditis and pericarditis following receipt of these vaccines, and the benefit of COVID-19 vaccination in reducing the risk of severe outcomes from COVID-19, including the possibility of cardiac sequelae.

- Counseling should include the need to seek care if symptoms of myocarditis or pericarditis, such as chest pain, shortness of breath, or palpitations develop after vaccination, particularly in the week after vaccination.

- In younger children, symptoms of myocarditis might also include non-specific symptoms such as irritability, vomiting, poor feeding, tachypnea, or lethargy.

- Extending the interval between the first and second doses to 8 weeks (i.e., extended interval) might reduce the rare risk of vaccine-associated myocarditis and pericarditis. The extended interval consideration applies only to children ages 6–23 months who are not moderately or severely immunocompromised and receive a multidose initial series (Table 1)

For additional information on COVID-19 vaccine and myocarditis or pericarditis, see the June 2025 ACIP presentation and the vaccine package inserts.

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 and there is no evidence of ongoing heart inflammation or sequelae.
- 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 COVID-19 (e.g., age, underlying medical 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 current Food and Drug Administration (FDA)-approved vaccine after the episode of myocarditis or pericarditis has completely resolved and there is no evidence of ongoing heart inflammation or sequelae. 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 COVID-19 vaccine.

Reporting vaccine adverse events

VAERS

For all licensed COVID-19 vaccines (Moderna [mNexspike, Spikevax], Novavax, Pfizer-BioNTech) healthcare providers are strongly encouraged to report to the Vaccine Adverse Event Reporting System (VAERS) the following:

- 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

Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967.

V-safe

V-safe is an active surveillance system to rapidly monitor for reactogenicity and health events after COVID-19 vaccination. Vaccine recipients can register to participate in V-safe through the V-safe website.

Clinical Considerations for Special Situations and Populations

AT A GLANCE

- People who recently had SARS-CoV-2 infection may consider delaying a COVID-19 vaccine dose by up to 3 months.
- Additional considerations apply to people with a history of multisystem inflammatory syndrome (MIS).

COVID-19 vaccination and prior SARS-CoV-2 infection

COVID-19 vaccination recommendations apply 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 up to 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.

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 hyperinflammatory immune response to SARS-CoV-2 infection. In 2023, MIS-C incidence had declined 98% since the peak of the COVID-19 pandemic despite continued SARS-CoV-2 transmission.

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, whether there is a causal relationship between COVID-19 vaccination and MIS-like illness is unknown.

Considerations for initiating COVID-19 vaccination in people with a history of MIS-C or MIS-A

Two studies (published in 2022 and 2023) found that children with a history of MIS-C were not at increased risk for the reoccurrence of MIS-C or other serious adverse events including myocarditis. Experts consider the benefits of COVID-19 vaccination for people with a history of MIS-C or MIS-A 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 vaccine 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 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.

Appendix: Vaccine Administration Errors and Deviations

AT A GLANCE

- 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 inserts 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 unapproved 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 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	• 2025–2026 mRNA vaccine administered to recipient 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.*
Product and dosage	• Higher-than-approved dose administered (e.g., incorrect dose volume, incorrect product resulting in higher-than-approved dose)	• Do not repeat dose.†
	• Lower-than-approved dose administered (e.g., leaked out of the syringe, equipment failure, recipient pulled away, incorrect product resulting in lower-than-approved dose)	• Repeat dose immediately with correct dose (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

Type	Administration error/deviation	Interim recommendation
		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 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).[‡]
	• mNexspike administered at a 2-month interval instead of the recommended 3-month interval	• Do not repeat dose.
Interchangeability[#]	• One dose of 2025–2026 mRNA vaccine and 1 dose of 2025–2026 Novavax vaccine (in any order) administered to previously unvaccinated moderately or severely immunocompromised	• Administer 1 dose of any 2025–2026 vaccine at least 4 weeks after the last dose to complete initial vaccination, followed by 1 dose of any 2025–2026 vaccine 6 months later (Table 2).

Type	Administration error/deviation	Interim recommendation
	recipient age 12 years and older	

*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 (i.e., extended interval) might reduce the rare risk of myocarditis and pericarditis associated with COVID-19 vaccines.

†If the administration error resulted in a higher-than-approved 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.

‡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 (i.e., extended interval) might reduce the rare risk of myocarditis and pericarditis associated with COVID-19 vaccines.

§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 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
- General Best Practices for Immunization

Previous updates

2025

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.

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.