Vaccines & Immunizations

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

Summary of recent changes (last updated 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.

Reference Materials

- Interim COVID-19 Immunization Schedule (Updated 5/31/2023)
- FAQs for the Interim Clinical Considerations (Updated 6/14/2023)
- COVID-19 Vaccination Recommendations Infographic (Updated 5/16/2023)
- COVID-19 Vaccination Recommendations Infographic (Immunocompromised) (Updated 5/16/2023)
- COVID-19 Vaccine Product Information (Updated 5/16/2023)
- Bivalent Moderna COVID-19 Vaccine: When to use the pink versus blue-capped vial (Updated 6/12/2023)

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What's this?

Overview of COVID-19 vaccination

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

- Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC)
- COVID-19 vaccine approval or Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA)
- CDC's Emergency Use Instructions (EUI) for FDA-approved vaccines
- Emergency Use Listing (EUL) of COVID-19 vaccines by the World Health Organization (WHO)
- ACIP's general best practice guidelines for immunization (GBPG)
- Expert opinion

COVID-19 vaccines

The following COVID-19 vaccines, categorized into three vaccine types, are currently authorized under an EUA by FDA and available for use in the United States:

- mRNA vaccines
  - Moderna COVID-19 Vaccine, Bivalent
  - Pfizer-BioNTech COVID-19 Vaccine, Bivalent
- Protein subunit vaccine

- Novavax COVID-19 Vaccine, Adjuvanted

The monovalent formulations of the two mRNA COVID-19 vaccines (COMIRNATY/Moderna COVID-19 Vaccine and SPIKEVAX/Pfizer-BioNTech COVID-19 Vaccine) should no longer be used for COVID-19 vaccination.

All currently available mRNA COVID-19 vaccines in the United States are formulated as a bivalent vaccine based on the original (ancestral) strain of SARS-CoV-2 and the Omicron BA.4 and BA.5 (BA.4/BA.5) variants of SARS-CoV-2.

Novavax COVID-19 Vaccine is formulated as a monovalent vaccine based on the original (ancestral strain) of SARS-CoV-2. Janssen COVID-19 Vaccine is no longer available in the United States.

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

COVID-19 vaccine-specific FDA fact sheets and U.S. COVID-19 Vaccine Product Information can be consulted for a full list of ingredients and 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-authorized COVID-19 vaccine for children younger than age 6 months. CDC recommends that people stay up to date with COVID-19 vaccination.

See Appendices A (People who received COVID-19 vaccine outside the United States) and B (People who received COVID-19 vaccine as part of a clinical trial) for recommendations for these populations.

Overview of the COVID-19 vaccination schedule

CDC recommends that people ages 6 months and older receive at least 1 bivalent mRNA COVID-19 vaccine.

An overview of COVID-19 vaccination is summarized below; detailed schedules can be found in Table 1 for people who are not moderately or severely immunocompromised and in Table 2 for people who are moderately or severely immunocompromised.

Bivalent mRNA vaccines

The number of bivalent doses varies by age, vaccine, previous COVID-19 vaccines received, and the presence of moderate or severe immune compromise.

For people who are not moderately or severely immunocompromised:

- 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 have the option to receive 1 additional bivalent mRNA vaccine dose

For people who are moderately or severely immunocompromised:

- 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 vaccine doses

Novavax COVID-19 Vaccine

People ages 12 years an older who previously received 1 or 2 monovalent Novavax primary series dose(s) are recommended to receive 1 bivalent mRNA vaccine dose. The monovalent Novavax COVID-19 Vaccine remains authorized for use as a 2-dose primary series and as a booster dose in certain limited situations.

Vaccine dosage and administration

In general, CDC recommends that people receive the age-appropriate vaccine product and dosage based on their age on the day of vaccination in accordance with the recommended intervals for that age group *(1)*. However, for COVID-19 vaccination there are exceptions for children who receive the Pfizer-BioNTech COVID-19 Vaccine and transition from age 4 to 5 years during the 3-dose vaccination series and children who transition from age 5 years to 6 years during the Moderna COVID-19 vaccination series (see Transitioning from a younger to older age group).

For additional guidance on vaccination in specific situations, see Considerations for extended intervals for COVID-19 vaccine doses and COVID-19 vaccination and SARS-CoV-2-infection.

Vaccine doses should be administered by the intramuscular route.

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

The COVID-19 vaccination schedule for people who are not moderately or severely immunocompromised is summarized in Table 1; see also COVID-19 Vaccination Recommendations Infographic .

The schedule is organized by age and COVID-19 vaccination history. It provides the number of bivalent mRNA vaccine doses an individual needs based on COVID-19 vaccine doses previously received, including the number of prior doses, whether the doses were monovalent or bivalent, and the vaccine manufacturer (Moderna, Novavax, or Pfizer-BioNTech).

Most people ages 6 years and older who are not moderately or severely immunocompromised and have received 1 dose of a bivalent mRNA vaccine do not need any further vaccine doses at this time. People ages 65 years and older who received 1 dose of a bivalent vaccine have the option to receive 1 additional dose at least 4 months after the first bivalent dose.

Table 1. Recommended COVID-19 vaccination schedule for people who are not moderately or severely immunocompromised by COVID-19 vaccination history, May 2023

mRNA COVID-19 vaccines

Ages 6 months–4 years

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
Unvaccinated	Moderna *___or___* Pfizer BioNTech†	2	0.25 mL/25 ug	Dark blue cap; gray label border	Dose 1 and Dose 2: 4–8 weeks*
		3	0.2 mL/3 ug	Maroon	Dose 1 and Dose 2: 3–8 weeks* Dose 2 and dose 3: At least 8 weeks
1 dose monovalent Moderna	Moderna	1	0.25 mL/25 ug	Dark blue cap; gray label border	4-8 weeks after monovalent dose*
2 doses monovalent Moderna	Moderna	1	0.2 mL/10 ug	Dark pink cap; label with yellow box	At least 8 weeks after last monovalent dose
2 doses monovalent Moderna and 1 dose bivalent Moderna	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
1 dose monovalent Pfizer-BioNTech	Pfizer BioNTech†	2	0.2 mL/3 ug	Maroon	Dose 1: 3–8 weeks after monovalent dose* Dose 1 and Dose 2: At least 8 weeks
2 doses monovalent Pfizer-BioNTech	Pfizer BioNTech	1	0.2 mL/3 ug	Maroon	At least 8 weeks after last monovalent dose
3 doses monovalent Pfizer-BioNTech	Pfizer BioNTech	1	0.2 mL/3 ug	Maroon	At least 8 weeks after last monovalent dose
2 doses monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer-BioNTech	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA

Age 5 years†

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
Unvaccinated	Moderna‡ ___*or*___ Pfizer BioNTech	2	0.25 mL/25 ug	Dark blue cap; gray label border	Dose 1 and Dose 2: 4–8 weeks*
		1	0.2 mL/10 ug	Orange	
1 dose monovalent Moderna	Moderna ___*or*___ Pfizer BioNTech	1	0.25 mL/25 ug	Dark blue cap; gray label border	4–8 weeks after monovalent dose*
		1	0.2 mL/10 ug	Orange	At least 8 weeks after monovalent dose
2 doses monovalent Moderna	Moderna ___*or*___ Pfizer BioNTech	1	0.2 mL/10 ug	Dark pink cap; label with yellow box	At least 8 weeks after last monovalent dose
		1	0.2 mL/10 ug	Orange	At least 8 weeks after last monovalent dose
2 doses monovalent Moderna and 1 dose bivalent mRNA	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA
1 or more doses monovalent Pfizer-BioNTech	Pfizer-BioNTech	1	0.2 mL/10 ug	Orange	At least 8 weeks after last monovalent dose
2 doses monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer-BioNTech	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA
Ever received 1 dose bivalent Pfizer-BioNTech (regardless of monovalent vaccine history)	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA

Ages 6–11 years‡

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
Unvaccinated	Moderna ___*or*___ Pfizer BioNTech	1	0.25 mL/25 ug	Dark blue cap; gray label border	—
		1	0.2 mL/10 ug	Orange	—
1 or more doses monovalent mRNA (no doses bivalent mRNA)	Moderna ___*or*___ Pfizer BioNTech	1	0.25 mL/25 ug	Dark blue cap; gray label border	At least 8 weeks after last monovalent dose
		1	0.2 mL/10 ug	Orange	At least 8 weeks after last monovalent dose
2 or more doses monovalent mRNA and 1 dose bivalent mRNA	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA
Ever received 1 dose bivalent mRNA (regardless of monovalent vaccine history)	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA

Ages 12 years and older

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
Unvaccinated	Moderna *___or___* Pfizer BioNTech	1	0.5 mL/50 ug	Dark blue cap; gray label border	—
		1	0.3 mL/30 ug	Gray	—
1 or more doses monovalent mRNA (no doses bivalent mRNA)	Moderna *___or___* Pfizer BioNTech	1	0.5 mL/50 ug	Dark blue cap; gray label border	At least 8 weeks after last monovalent dose
		1	0.3 mL/30 ug	Gray	At least 8 weeks after last monovalent dose
Ever received 1 dose bivalent mRNA (regardless of monovalent vaccine history)	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA
People ages 65 years and older have the option to receive 1 additional bivalent mRNA vaccine dose at least 4 months after the first dose of a bivalent mRNA vaccine. If Moderna is used, administer 0.5 mL/50 ug (dark blue cap and label with a gray border); if Pfizer-BioNTech is used, administer 0.3 mL/30 ug (gray cap and label with a gray border).					

Abbreviation: NA = not authorized

*An **8-week** interval between the first and second mRNA COVID-19 vaccine (Moderna, Pfizer-BioNTech) doses (i.e., a bivalent mRNA vaccine dose administered as a second dose after either 1 bivalent mRNA vaccine dose or 1 previously received monovalent mRNA vaccine dose) might be optimal for some people as it might reduce the small risk of myocarditis and pericarditis associated with these vaccines.

†The FDA EUA requires that children who initiate the Pfizer-BioNTech vaccination series at age 4 years and transition to age 5 years during the series receive all 3 doses with bivalent Pfizer-BioNTech COVID-19 Vaccine (0.2 mL/3 ug; maroon cap and label with a maroon border). Children who previously received 1 or 2 doses of monovalent Pfizer-BioNTech vaccine at age 4 years and transition to age 5 years should receive the remaining dose(s) needed to complete the 3-dose series with bivalent Pfizer-BioNTech vaccine for ages 6 months–4 years (0.2 mL/3 ug; maroon cap and label). Dose 1 and 2 are separated by 3–8 weeks and dose 2 and 3 are separated by at least 8 weeks.

‡Children who initiate the Moderna vaccination series at age 5 years and transition to age 6 years during the series should receive 2 doses of bivalent Moderna COVID-19 Vaccine (0.25 mL/25 ug; dark blue cap and label with a gray border). Children who previously received 1 dose of monovalent Moderna vaccine at age 5 years and transition to age 6 years should receive 1 dose of bivalent Moderna vaccine (0.25 mL/25 ug; dark blue cap and label with a gray border). The bivalent Moderna vaccine dose is administered 4–8 weeks after the monovalent Moderna vaccine dose.

Novavax COVID-19 Vaccine

People ages 12 years and older who previously received 1 or more doses of Novavax COVID-19 Vaccine are recommended to receive 1 bivalent mRNA vaccine dose.

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
1 or more doses of Novavax vaccine	Moderna *___or___* Pfizer BioNTech	1	0.5 mL/50 ug	Dark blue cap; gray label border	At least 8 weeks after last monovalent dose
		1	0.3 mL/30 ug	Gray	At least 8 weeks after last monovalent dose
People ages 65 years and older have the option to receive 1 additional bivalent mRNA vaccine dose at least 4 months after the first dose of a bivalent mRNA vaccine. If Moderna is used, administer 0.5 mL/50 ug (dark blue cap and label with a gray border); if Pfizer-BioNTech is used, administer 0.3 mL/30 ug (gray cap and label with a gray border).					

Novavax COVID-19 Vaccine remains authorized to provide:

- A 2-dose primary series to people ages 12 years and older. The primary series doses are separated by 3–8 weeks. An 8-week interval between the first and second primary series doses might be optimal for some people ages 6 months–64 years, especially for males ages 12–39 years, as it might reduce the small risk of myocarditis and pericarditis associated with this vaccine.
- A booster dose in limited situations to people ages 18 years and older who previously completed primary vaccination using any FDA-approved or FDA-authorized COVID-19 vaccine; have not received any previous booster dose(s); and are unable (i.e., mRNA vaccine contraindicated or vaccine not available) or unwilling to receive an mRNA vaccine and would otherwise not receive a booster dose. The monovalent Novavax booster dose is administered **at least 6 months** after completion of any primary series.

Previous vaccination with Janssen COVID-19 Vaccine

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

Considerations for people ages 65 years and older to receive an additional bivalent mRNA vaccine dose

People ages 65 years and older have the option to receive 1 additional bivalent mRNA vaccine dose if it has been at least 4 months after their first bivalent mRNA vaccine dose. The option to receive 1 additional bivalent mRNA vaccine dose may be informed by the clinical judgement of a healthcare provider, a person's risk for severe COVID-19 due to the presence of underlying medial conditions and age, and personal preference and circumstances.

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 (i.e., a bivalent mRNA vaccine dose administered as a second dose after either 1 bivalent mRNA vaccine dose or 1 previously received monovalent mRNA vaccine dose) and between the first and second doses of monovalent Novavax COVID-19 Vaccine might be optimal for some people as it might reduce the small risk of myocarditis and pericarditis associated with these COVID-19 vaccines. Under the current COVID-19 vaccination schedule, the extended interval applies only to children ages 6 months–5 years, depending on their vaccination history and which mRNA vaccine is administered (Table 1), and people ages 12 years and older receiving Novavax vaccine.

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.

Some studies in adolescents (ages 12–17 years) and adults have shown the small risk of myocarditis and pericarditis associated with mRNA COVID-19 vaccines might be reduced and peak antibody responses and vaccine effectiveness might be increased with an interval longer than 4 weeks. Extending the interval beyond 8 weeks has not been shown to provide additional benefit.

A 3-week interval between the first and second doses of Novavax and Pfizer-BioNTech COVID-19 vaccines and a 4-week interval between the first and second doses of Moderna COVID-19 Vaccine continue to be recommended for people who are moderately or severely immunocompromised, adults ages 65 years and older, and in situations when the fullest possible protection needs to be achieved sooner (e.g., increased concern about an individual's higher risk for severe disease).

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

To assist healthcare providers, the COVID-19 vaccination schedule for people who are moderately or severely immunocompromised (Table 2) provides detailed age-specific guidance; see also COVID-19 Vaccination Recommendations Infographic (Immunocompromised) . However, the EUAs for Moderna and Pfizer-BioNTech COVID-19 vaccines allow healthcare providers flexibility for use of vaccine products, number of doses, dosage, and intervals between doses; alternative schedules within the parameters of the EUAs may be appropriate based on individual circumstances and clinical judgement.

People who are or who become moderately or severely immunocompromised should follow the COVID-19 vaccination schedule according to their age and immune status at the time of eligibility for that dose; see Considerations for timing of COVID-19 vaccination in relation to immunosuppressive therapies for vaccination of people who will shortly become

moderately or severely immunocompromised (e.g., prior to organ transplant) and Considerations for COVID-19 revaccination.

Table 2. Recommended COVID-19 vaccination schedule for people who are moderately or severely immunocompromised by COVID-19 vaccination history, May 2023

mRNA COVID-19 vaccines

Ages 6 months–4 years

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated*	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
Unvaccinated	Moderna *or* Pfizer BioNTech†	3	0.25 mL/25 ug	Blue cap; gray label border	Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: At least 4 weeks
		3	0.2 mL/3 ug	Maroon	Dose 1 and Dose 2: 3 weeks Dose 2 and dose 3: At least 8 weeks
1 dose monovalent Moderna	Moderna	2	0.25 mL/25 ug	Blue cap; gray label border	Dose 1: 4 weeks after monovalent dose Dose 1 and Dose 2: At least 4 weeks
2 doses monovalent Moderna	Moderna	1	0.25 mL/25 ug	Blue cap; gray label border	At least 4 weeks after last monovalent dose
3 doses monovalent Moderna	Moderna	1	0.2 mL/10 ug	Dark pink cap; label with yellow box	At least 8 weeks after last monovalent dose
3 doses monovalent Moderna and 1 dose bivalent Moderna	—	See footnote	—	—	—
1 dose monovalent Pfizer-BioNTech	Pfizer-BioNTech†	2	0.2 mL/3 ug	Maroon	Dose 1: 3 weeks after monovalent dose Dose 1 and Dose 2: At least 8 weeks
2 doses monovalent Pfizer-BioNTech	Pfizer-BioNTech	1	0.2 mL/3 ug	Maroon	At least 8 weeks after last monovalent dose
3 doses monovalent Pfizer-BioNTech	Pfizer-BioNTech	1	0.2 mL/3 ug	Maroon	At least 8 weeks after last monovalent dose
2 doses monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer-BioNTech	—	See footnote	—	—	—
3 doses of monovalent Pfizer-BioNTech and 1 bivalent Pfizer-BioNTech dose	—	See footnote	—	—	—

*People ages 6 months–4 years who are moderately or severely immunocompromised have the option to receive 1 additional dose of a homologous bivalent mRNA vaccine at least 2 months following the last recommended bivalent mRNA COVID-19 vaccine dose. Further additional homologous bivalent dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose. For Moderna, 0.2mL/10 ug (dark pink cap and label with a yellow box) is recommended; 0.25/25 ug (dark blue cap and label with a gray border) is also authorized. For Pfizer-BioNTech, administer 0.2 mL/3 ug (maroon cap and label with a maroon border).

†The FDA EUA requires that children who initiate the Pfizer-BioNTech vaccination series at age 4 years and transition to age 5 years during the series receive all 3 doses with bivalent Pfizer-BioNTech COVID-19 Vaccine (0.2 mL/3 ug; maroon cap and label with a maroon border).

Ages 5 years*

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated†	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
Unvaccinated	Moderna‡ *or* Pfizer BioNTech	3	0.25 mL/25 ug	Blue cap; gray label border	Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: At least 4 weeks
		3	0.2 mL/10 ug	Orange	Dose 1 and Dose 2: 3 weeks Dose 2 and dose 3: At least 4 weeks

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated†	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
1 dose monovalent Moderna	Moderna‡	2	0.25 mL/25 ug	Blue cap; gray label border	Dose 1: 4 weeks after monovalent dose Dose 1 and Dose 2: At least 4 weeks
2 doses monovalent Moderna	Moderna‡	1	0.25 mL/25 ug	Blue cap; gray label border	At least 4 weeks after last monovalent dose
3 doses monovalent Moderna	Moderna ___*or*___ Pfizer BioNTech	1	0.25 mL/25 ug	Blue cap; gray label border	At least 8 weeks after last monovalent dose
		1	0.2 mL/10 ug	Orange	At least 8 weeks after last monovalent dose
3 doses monovalent Moderna and 1 dose bivalent mRNA	—	See footnote	—	—	—
1 dose monovalent Pfizer-BioNTech	Pfizer-BioNTech	2	0.2 mL/10 ug	Orange	Dose 1: 3 weeks after monovalent dose Dose 1 and Dose 2: At least 4 weeks
2 doses monovalent Pfizer-BioNTech	Pfizer-BioNTech	1	0.2 mL/10 ug	Orange	At least 4 weeks after last monovalent dose
3 doses monovalent Pfizer-BioNTech	Pfizer-BioNTech	1	0.2 mL/10 ug	Orange	At least 8 weeks after last monovalent dose
3 doses monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer-BioNTech	—	See footnote	—	—	—

*The FDA EUA requires that children who initiate the Pfizer-BioNTech vaccination series at age 4 years and transition to age 5 years during the series receive all 3 doses with bivalent Pfizer-BioNTech COVID-19 Vaccine (0.2 mL/3 ug; maroon cap and label with a maroon border). Children who previously received 1 or 2 doses of monovalent Pfizer-BioNTech vaccine at age 4 years and transition to age 5 years should receive the remaining dose(s) needed to complete the 3-dose series with bivalent Pfizer-BioNTech vaccine for ages 6 months–4 years (0.2 mL/3 ug; maroon cap and label). Dose 1 and 2 are separated by 3 weeks and dose 2 and 3 are separated by at least 8 weeks.

†People age 5 years who are moderately or severely immunocompromised have the option to receive 1 additional dose of a bivalent mRNA vaccine at least 2 months following the last recommended bivalent mRNA COVID-19 vaccine dose. Further additional bivalent dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose. People in this age group who previously received a dose(s) of Pfizer-BioNTech vaccine are authorized to receive only Pfizer-BioNTech vaccine. Recipients who previously received Moderna vaccine are authorized to receive either bivalent mRNA vaccine.

- If Moderna is used, 0.2mL/10 ug (dark pink cap and label with a yellow box) is recommended; 0.25/25ug (dark blue cap and label with a gray border) is also authorized.
- If Pfizer-BioNTech is used, administer 0.2 ml/10 ug (orange cap and label with an orange border).

‡Pfizer-BioNTech COVID-19 Vaccine (0.2 mL/10 ug; orange cap and label with an orange border) is also authorized in this age group with this vaccination history, including people initiating vaccination. Use a 4-week interval between Dose 1 and Dose 2 of a mixed product 3-dose bivalent vaccination series and between 1 prior monovalent vaccine dose and a heterologous first bivalent vaccine dose.

Ages 6-11 years

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated*	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
Unvaccinated	Moderna† ___*or*___ Pfizer-BioNTech‡	3	0.25 mL/25 ug	Blue cap; gray label border	Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: At least 4 weeks
		3	0.2 mL/10 ug	Orange	Dose 1 and Dose 2: 3 weeks Dose 2 and dose 3: At least 4 weeks
1 dose monovalent Moderna	Moderna†	2	0.25 mL/25 ug	Blue cap; gray label border	Dose 1: 4 weeks after monovalent dose Dose 1 and Dose 2: At least 4 weeks
2 doses monovalent Moderna	Moderna†	1	0.25 mL/25 ug	Blue cap; gray label border	At least 4 weeks after last monovalent dose

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated*	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
3 doses monovalent Moderna	Moderna ___*or*___ Pfizer-BioNTech	1	0.25 mL/25 ug	Blue cap; gray label border	At least 8 weeks after last monovalent dose
		1	0.2 mL/10 ug	Orange	At least 8 weeks after last monovalent dose
3 doses monovalent Moderna and 1 dose bivalent mRNA	—	See footnote	—	—	—
1 dose monovalent Pfizer-BioNTech	Pfizer-BioNTech‡	2	0.2 mL/10 ug	Orange	Dose 1: 3 weeks after monovalent dose Dose 1 and Dose 2: At least 4 weeks
2 doses monovalent Pfizer-BioNTech	Pfizer-BioNTech‡	1	0.2 mL/10 ug	Orange	At least 4 weeks after last monovalent dose
3 doses monovalent Pfizer-BioNTech	Moderna ___*or*___ Pfizer-BioNTech	1	0.25 mL/25 ug	Blue cap; gray label border	At least 8 weeks after last monovalent dose
		1	0.2 mL/10 ug	Orange	At least 8 weeks after last monovalent dose
3 doses monovalent Pfizer-BioNTech and 1 dose bivalent mRNA	—	See footnote	—	—	—

*People ages 6–11 years who are moderately or severely immunocompromised have the option to receive 1 additional dose of Moderna COVID-19 Vaccine (0.25mL/25 ug; dark blue cap and label with a gray border) or Pfizer-BioNTech COVID-19 Vaccine (0.2 mL/10 ug; orange cap and label with an orange border) at least 2 months following the last recommended bivalent COVID-19 vaccine dose. Further additional dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose.

†Pfizer-BioNTech COVID-19 Vaccine (0.2 mL/10 ug; orange cap and label with an orange border) is also authorized in this age group with this vaccination history, including people initiating vaccination. Use a 4-week interval between Dose 1 and Dose 2 of a mixed product 3-dose bivalent vaccination series and between 1 prior monovalent vaccine dose and a heterologous first bivalent vaccine dose.

‡Moderna COVID-19 Vaccine (0.25 ml/25 ug; dark blue cap and label with a gray border) is also authorized in this age group with this vaccination history, including people initiating vaccination. Use a 4-week interval between Dose 1 and Dose 2 of a mixed product 3-dose bivalent vaccination series and between 1 prior monovalent vaccine dose and a heterologous first bivalent vaccine dose.

Ages 12 years and older

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated*	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
Unvaccinated	Moderna† ___*or*___ Pfizer-BioNTech‡	3	0.5 mL/50 ug	Blue cap; gray label border	Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: At least 4 weeks
		3	0.3 mL/30 ug	Gray	Dose 1 and Dose 2: 3 weeks Dose 2 and dose 3: At least 4 weeks
1 dose monovalent Moderna	Moderna†	2	0.5 mL/50 ug	Blue cap; gray label border	Dose 1: 4 weeks after monovalent dose Dose 1 and Dose 2: At least 4 weeks
2 doses monovalent Moderna	Moderna†	1	0.5 mL/50 ug	Blue cap; gray label border	At least 4 weeks after last monovalent dose
3 doses monovalent Moderna	Moderna ___*or*___ Pfizer-BioNTech	1	0.5 mL/50 ug	Blue cap; gray label border	At least 8 weeks after last monovalent dose
		1	0.3 mL/30 ug	Gray	At least 8 weeks after last monovalent dose
3 doses monovalent Moderna and 1 dose bivalent mRNA	—	See footnote	—	—	—

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated*	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
1 dose monovalent Pfizer-BioNTech	Pfizer-BioNTech‡	2	0.3 mL/30 ug	Gray	Dose 1: 3 weeks after monovalent dose Dose 1 and Dose 2: At least 4 weeks
2 doses monovalent Pfizer	Pfizer-BioNTech‡	1	0.3 mL/30 ug	Gray	At least 4 weeks after last monovalent dose
3 doses monovalent Pfizer-BioNTech	Moderna ___*or*___ Pfizer-BioNTech	1	0.5 mL/50 ug	Blue cap; gray label border	At least 8 weeks after last monovalent dose
		1	0.3 mL/30 ug	Gray	At least 8 weeks after last monovalent dose
3 doses monovalent Pfizer-BioNTech and 1 dose bivalent mRNA	—	See footnote	—	—	—

*People ages 12 years and older who are moderately or severely immunocompromised have the option to receive 1 additional dose of Moderna COVID-19 Vaccine (0.5 mL/50 ug; dark blue cap and label with a gray border) or Pfizer-BioNTech COVID-19 Vaccine (0.3 mL/30 ug; gray cap and label with a gray border) at least 2 months following the last recommended bivalent COVID-19 vaccine dose. Further additional dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose.

†Pfizer-BioNTech COVID-19 Vaccine is also authorized in this age group with this vaccination history (0.3 mL/30 ug; gray cap and label with a gray border), including people initiating vaccination. Use a 4-week interval between Dose 1 and Dose 2 of a mixed product 3-dose bivalent vaccination series and between 1 prior monovalent vaccine dose and a heterologous first bivalent vaccine dose.

‡Moderna COVID-19 Vaccine is also authorized in this age group with this vaccination history (0.5 ml/50 ug; dark blue cap and label with a gray border), including people initiating vaccination. Use a 4-week interval between Dose 1 and Dose 2 of a mixed product 3-dose bivalent vaccination series and between 1 prior monovalent vaccine dose and a heterologous first bivalent vaccine dose.

Novavax COVID-19 Vaccine

People ages 12 years and older who previously received 1 or more doses of Novavax COVID-19 Vaccine are recommended to receive 1 bivalent mRNA vaccine dose.

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated*	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
1 or 2 doses of Novavax vaccine	Moderna ___*or*___ Pfizer BioNTech	1	0.50 mL/50 ug	Dark blue cap; gray label border	At least 8 weeks after last monovalent dose
		1	0.3 mL/30 ug	Gray	At least 8 weeks after last monovalent dose

*People ages 12 years and older who are moderately or severely immunocompromised have the option to receive 1 additional dose of Moderna COVID-19 Vaccine (0.5 mL/50 ug; dark blue cap and label with a gray border) or Pfizer-BioNTech COVID-19 Vaccine (0.3 mL/30 ug; gray cap and label with a gray border) at least 2 months following the last recommended bivalent COVID-19 vaccine dose. Further additional dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose.

Novavax COVID-19 Vaccine remains authorized to provide:

- A 2-dose primary series to people ages 12 years and older. The primary series doses are separated by 3 weeks.
- A booster dose in limited situations to people ages 18 years and older who previously completed primary vaccination using any FDA-approved or FDA-authorized COVID-19 vaccine; have not received any previous booster dose(s); and are unable (i.e., contraindicated or vaccine not available) or unwilling to receive an mRNA vaccine and would otherwise not receive a booster dose. The monovalent Novavax booster dose is administered **at least 6 months** after completion of any primary series.

Previous vaccination with Janssen COVID-19 Vaccine

The following guidance is for people who are moderately or severely immunocompromised ages 18 years and older who previously received the Janssen COVID-19 Vaccine primary series dose:

- People who have not received a bivalent mRNA vaccine dose should receive 1 bivalent mRNA vaccine dose at least 4 weeks after the primary series dose or 4 weeks after their last monovalent dose (i.e., a monovalent additional dose or a monovalent mRNA booster dose). People have the option to receive 1 additional bivalent COVID-19 mRNA vaccine dose

at least 2 months after the recommended bivalent COVID-19 vaccine dose. Further additional dose(s) may be administered, informed by the clinical judgment of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose.

- People who have received 1 bivalent mRNA vaccine dose have the option to receive 1 additional bivalent COVID-19 mRNA vaccine dose at least 2 months after the previously received bivalent COVID-19 vaccine dose. Further additional dose(s) may be administered, informed by the clinical judgment of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose.

Description of moderate and severe immunocompromising conditions and treatment

Moderate and severe immunocompromising conditions and treatments include **but are not limited to**:

- Active treatment for solid tumor and hematologic malignancies
- Hematologic malignancies associated with poor responses to COVID-19 vaccines regardless of current treatment status (e.g., chronic lymphocytic leukemia, non-Hodgkin lymphoma, multiple myeloma, acute leukemia)
- Receipt of solid-organ transplant or an islet transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic cell transplant (HCT) (within 2 years of transplantation or taking immunosuppressive therapy)
- Moderate or severe primary immunodeficiency (e.g., common variable immunodeficiency disease, severe combined immunodeficiency, DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced HIV infection (people with HIV and CD4 cell counts less than 200/mm^3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV) or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., 20 mg or more of prednisone or equivalent per day when administered for 2 or more weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell-depleting agents)

Factors to consider in assessing the general level of immune competence in a patient include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment.

For additional information about the degree of immune suppression associated with different medical conditions and treatments, providers can consult ACIP's general best practices for vaccination of people with altered immunocompetence, the CDC Yellow Book, and the Infectious Diseases Society of America policy statement, 2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host .

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.

COVID-19 vaccination and EVUSHELD™

As of January 26, 2023, tixagevimab/cilgavimab (EVUSHELD™), a combination of two monoclonal antibodies, is not currently authorized for use in the United States. EVUSHELD™ was previously recommended for pre-exposure prophylaxis to supplement vaccine protection; however, SARS-CoV-2 variants currently circulating in the United States are resistant to EVUSHELD™.

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Timing, spacing, age transitions, and coadministration of COVID-19 vaccines

4-Day grace period

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

Transitioning from a younger to older age group

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

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

- The FDA EUA requires that children who initiate the Pfizer-BioNTech 3-dose vaccination series at age 4 years and transition to age 5 years during the series must complete the series they start and receive all 3 doses with bivalent Pfizer-BioNTech COVID-19 Vaccine (0.2 mL/3 ug; maroon cap and label with a maroon border). Children who previously received 1 or 2 doses of monovalent Pfizer-BioNTech vaccine at age 4 years and transition to age 5 years should receive the remaining dose(s) needed to complete the 3-dose series with bivalent Pfizer-BioNTech vaccine for ages 6 months–4 years (0.2 mL/3 ug; maroon cap and label).
- Children who initiate the Moderna vaccination series at age 5 years and transition to age 6 years during the series should receive 2 doses of bivalent Moderna COVID-19 Vaccine (0.25 mL/25 ug; dark blue cap and label with a gray border). Children who previously received 1 dose of monovalent Moderna COVID-19 Vaccine at age 5 years and transition to age 6 years should receive 1 dose of bivalent Moderna vaccine (0.25 mL/25 ug; dark blue cap and gray border).

Coadministration of COVID-19 vaccines with other vaccines

In accordance with general best practices, routine administration of all age-appropriate doses of vaccines simultaneously (i.e., administering more than one vaccine on the same clinic day or "coadministration") is recommended for children, adolescents, and adults if there are no contraindications at the time of the healthcare visit. However, there are additional considerations if administering an orthopoxvirus vaccine as described below.

Orthopoxvirus vaccination

- 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.

For best practices for administering multiple injections, see ACIP's general best practices and *Epidemiology and Prevention of Vaccine-Preventable Diseases* (Pink Book).

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Interchangeability of COVID-19 vaccines

CDC recommends children ages 6 months–5 years who are unvaccinated and recommended to receive more than 1 bivalent mRNA vaccine dose for initial vaccination receive all doses from the same manufacturer. However, as detailed below, FDA authorization allows for administration of a mixed product series for initial vaccination in some age groups.

Authorization to use COVID-19 vaccines interchangeably from different manufacturers varies by vaccination history, age, and product as follows:

- People ages 6 months–4 years who are unvaccinated or previously received 1 or more doses of a monovalent mRNA vaccine are authorized to receive only bivalent mRNA vaccine dose(s) from the same vaccine manufacturer.
- People age 5 years who are unvaccinated or previously received 1 or more doses of monovalent Moderna COVID-19 Vaccine are authorized to receive either bivalent Moderna or bivalent Pfizer-BioNTech COVID-19 vaccine.
- People age 5 years who are unvaccinated or previously received 1 or more doses of monovalent Pfizer-BioNTech COVID-19 are authorized to receive only bivalent Pfizer-BioNTech COVID-19 Vaccine.
- People ages 6 years and older who are unvaccinated or previously received 1 or more doses of any monovalent COVID-19 vaccine are authorized to receive either bivalent Moderna or bivalent Pfizer-BioNTech COVID-19 vaccine.

A Vaccine Adverse Event Reporting System (VAERS) report is required following administration of a vaccine in an unauthorized manner.

In the following exceptional situations, a different age-appropriate COVID-19 vaccine may be administered when FDA authorization requires that a vaccine from the same manufacturer be used. A VAERS report is not required for these exceptional situations:

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

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

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Vaccination and SARS-CoV-2 laboratory testing

Pre-vaccination testing

Antibody testing is not currently recommended to assess the need for vaccination in an unvaccinated person or to assess immunity to SARS-CoV-2 following COVID-19 vaccination. If antibody testing is done, vaccination should be completed as recommended regardless of the antibody test result.

Interpretation of SARS-CoV-2 test results in vaccinated people

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

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

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Patient counseling

Pre-vaccination counseling

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

- Local reactions include pain/tenderness, swelling, and erythema at the injection site.
- Systemic reactions include fever, fatigue/malaise, headache, chills, myalgia, arthralgia; among younger children, particularly those younger than age 3 years, systemic reactions also can include irritability/crying, sleepiness, and loss of appetite.
- Antipyretic or analgesic medications can be taken for the treatment of post-vaccination local or systemic symptoms but should not be used prophylactically for prevention of post-vaccination symptoms. In general, aspirin is not recommended for use in children and adolescents ages 17 years and younger as an antipyretic or analgesic due to the risk of Reye's syndrome.

Localized axillary lymphadenopathy on the same side as the vaccinated arm or groin, if vaccination was in the thigh, has been observed following vaccination with Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines *(2)*. Infrequently, people who have received dermal fillers might experience temporary swelling at or near the site of filler injection (usually face or lips) following a dose of an mRNA COVID-19 vaccine.

Unless people have a contraindication to vaccination, they should be encouraged to complete vaccination to optimize protection against COVID-19 even if they experience local or systemic symptoms following a vaccine dose.

Myocarditis and pericarditis: People receiving any COVID-19 vaccine, especially males ages 12–39 years, should be made aware of the rare risk of myocarditis and pericarditis following COVID-19 vaccination. Counseling should include the need to seek care if symptoms of myocarditis or pericarditis develop after vaccination, particularly in the week after vaccination. See COVID-19 vaccination and myocarditis and pericarditis for additional information.

Anaphylactic reactions: Anaphylactic reactions have been rarely reported following receipt of COVID-19 vaccines. Administration of antihistamines before COVID-19 vaccination to prevent allergic reactions is not generally recommended. However, while antihistamines will not prevent anaphylaxis, some experts advise antihistamine use as a means of preventing milder allergic reactions in patients who might be at higher risk for allergic reactions. For more information on the assessment and potential management of anaphylaxis, see Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination.

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 GBPG, vaccination providers, particularly when vaccinating adolescents, should consider observing vaccine recipients for 15 minutes after vaccination.

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

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

See also Contraindications and precautions.

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Contraindications and precautions

CDC considers COVID-19 vaccination to be contraindicated or a precaution in certain situations (Table 3).

Table 3. Contraindications and precautions to COVID-19 vaccination

Medical condition or history	Guidance	Recommended action(s)
History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine*	Contraindication	Do not vaccinate with the same type of COVID-19 vaccine.*
History of a known diagnosed allergy to a component of the COVID-19 vaccine†	Contraindication	Do not vaccinate with a COVID-19 vaccine that contains that component.*

Medical condition or history	Guidance	Recommended action(s)
History of anaphylaxis after any vaccine other than COVID-19 vaccine or after any injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"])*	Precaution	The benefit of vaccination outweighs the risks for most people.*
People with a history of a non-severe, immediate (onset less than 4 hours) allergic reaction after a dose of one type of COVID-19 vaccine have a precaution to the **same type of COVID-19 vaccine.***	Precaution	
People with an allergy-related contraindication to one type of COVID-19 vaccine have a precaution to the **other type of COVID-19 vaccine.**	Precaution	
Moderate or severe acute illness, with or without fever	Precaution	Defer vaccination until the illness has improved.
History of MIS-C or MIS-A	Precaution	See COVID-19 vaccination and MIS-C and MIS-A.
History of myocarditis or pericarditis after a dose of **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 for additional considerations.

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

*See Appendix D for definitions of allergic reactions, and risk assessment and triage of people with a history of allergies or allergic reactions.

†See FDA EUA fact sheets for a full list of vaccine ingredients.

Healthcare professionals and health departments may request a consultation from the Clinical Immunization Safety Assessment COVIDvax project for a complex COVID-19 vaccine safety question not readily addressed by CDC guidance.

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Reporting of vaccine adverse events

Adverse events that occur in a recipient following COVID-19 vaccination should be reported to VAERS. Vaccination providers are required by FDA and the provider agreement for the CDC COVID-19 Vaccination Program to report the following that occur after any COVID-19 vaccination:

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events , irrespective of attribution to vaccination
- Cases of Multisystem Inflammatory Syndrome (MIS) in adults and children
- Cases of myocarditis
- Cases of pericarditis
- Cases of COVID-19 that result in hospitalization or death

Reporting is encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967.

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Safety considerations for mRNA COVID-19 vaccines: Moderna and Pfizer-BioNTech

In clinical trials of Moderna and Pfizer-BioNTech COVID-19 vaccines, types of post-vaccination reactions were generally similar. The most frequent reported reactions, by age group, follow below.

Older children, adolescents, and adults

- Local: Pain at the injection site, sometimes severe
- Systemic: Fatigue, headache, and myalgia

Overall, symptoms tended to be more frequent and severe following the second dose of vaccine and among adolescents and younger adults compared with older adults.

Younger children (ages 6 months–5 years)

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

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

Febrile seizures can occur in infants and young children ages 6 months–5 years with any condition that causes a fever (most common with high fevers), including COVID-19 . Febrile seizures are uncommon after vaccination and were rare in mRNA COVID-19 vaccine clinical trials for infants and young children. In rare instances, administration of certain combination vaccines or more than one vaccine at the same clinic visit has been associated with an increased risk of febrile seizures in infants and young children. The impact of coadministration of COVID-19 and routine vaccines on the risk of febrile seizures has not been specifically studied. CDC is monitoring for febrile seizures following COVID-19 vaccination in infants and young children.

See also COVID-19 vaccination and myocarditis and pericarditis and vaccine reactions and adverse events for Moderna and Pfizer-BioNTech mRNA COVID-19 vaccines.

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Safety considerations for Novavax COVID-19 Vaccine

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

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

Most symptoms were mild to moderate in severity and resolved within 1–3 days. Overall, symptoms were more frequent in people ages 12–64 years compared to people ages 65 years and older and more frequent after dose 2 than dose 1 of the primary series. Among adults ages 18 years and older who received the Novavax booster dose, symptoms were more frequently reported after the booster dose than dose 2 of the primary series.

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

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COVID-19 vaccination and myocarditis and pericarditis

Considerations for COVID-19 vaccination

Cases of myocarditis and pericarditis have rarely been observed following receipt of COVID-19 vaccines used in the United States. Evidence from multiple monitoring systems in the United States and globally support a causal association for mRNA COVID-19 vaccines (Moderna or Pfizer-BioNTech) and myocarditis and pericarditis. Data from clinical trials of Novavax COVID-19 Vaccine and global vaccine safety monitoring systems 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 (see mRNA COVID-19 vaccines and Novavax COVID-19 Vaccine), ACIP and CDC determined that the benefits (e.g., prevention of COVID-19 and its severe outcomes) outweigh the rare risk of myocarditis and pericarditis in all populations recommended for vaccination.
- Extending the interval to 8 weeks between the first and second doses for some people might reduce the rare risk of vaccine-associated myocarditis and pericarditis; see Considerations for extended intervals for COVID-19 vaccination for more information.
- People, especially males ages 12–39 years, should be made aware of the rare risk of myocarditis and pericarditis following receipt of these vaccines and the benefit of COVID-19 vaccination in reducing the risk of severe outcomes from COVID-19, including the possibility of cardiac sequelae.
    - Counseling should include the need to seek care if symptoms of myocarditis or pericarditis, such as chest pain, shortness of breath, or tachycardia 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.

Myocarditis or pericarditis after a dose of COVID-19 vaccine

Development of myocarditis or pericarditis 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. Until additional safety data are available, experts advise that these people should:

- Generally **not receive** a subsequent dose of any COVID-19 vaccine
- If, after a risk assessment, the decision is made to administer a subsequent COVID-19 vaccine dose, wait until at least after their episode of myocarditis or pericarditis has resolved (resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by patient's clinical team)

Considerations for subsequent COVID-19 vaccination might include:

- Myocarditis or pericarditis considered unrelated to vaccination (e.g., due to SARS-CoV-2 or other viruses), especially if the diagnosis of myocarditis or pericarditis occurred more than 3 weeks after the most recent dose of COVID-19 vaccine
- Personal risk of severe acute COVID-19 (e.g., age, underlying conditions)
- Timing of any immunomodulatory therapies; ACIP's general best practice guidelines for immunization can be consulted for more information

Safety monitoring is ongoing to further assess the known and potential risks for myocarditis and pericarditis after COVID-19 vaccination in all age groups. CDC is also assessing the long-term effects of myocarditis in people with myocarditis after COVID-19 vaccination.

For myocarditis associated with MIS-C or MIS-A, see COVID-19 vaccination and MIS-C and MIS-A.

History of myocarditis or pericarditis prior to COVID-19 vaccination

People who have a history of myocarditis or pericarditis unrelated to COVID-19 vaccination (e.g., due to SARS-CoV-2 or other viruses) may receive any currently 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). For people who have a history of myocarditis associated with MIS-C or MIS-A, see COVID-19 vaccination and MIS-C and MIS-A.

History of other heart disease

People who have a history of other heart disease, including congenital heart disease and Kawasaki disease, may receive any currently FDA-authorized COVID-19 vaccine.

mRNA COVID-19 vaccines

Adolescents and young adults

- Cases of myocarditis and pericarditis have rarely occurred after mRNA COVID-19 vaccines. 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 after dose 1 and booster doses.
- The reporting rates for myocarditis after mRNA COVID-19 primary series vaccination or booster vaccination exceed the background rates in several age groups in males and females with the highest rates observed in males ages 12–39 years; see the June 23, 2022 and September 1, 2022 ACIP meetings for more information.
- Based on the overall data to date, the risk for myocarditis and pericarditis after an mRNA COVID-19 booster dose in adolescents and young adults appears generally similar to or lower than the risk after a second mRNA COVID-19 vaccine primary series dose.
- In age groups where product comparisons can be made (i.e., 18–39 years), some evidence suggests that the risk of myocarditis and pericarditis might be higher following vaccination with Moderna COVID-19 Vaccine relative to Pfizer-BioNTech COVID-19 Vaccine; however, findings are not consistent in all U.S. monitoring systems.

Children

- In post-authorization surveillance , cases of myocarditis and pericarditis among children ages 5–11 years after Pfizer-BioNTech COVID-19 vaccination have been rarely reported, primarily in males and after dose 2; the reporting rate of myocarditis in VAERS following dose 2 of Pfizer-BioNTech marginally exceeded the background incidence rate for male children in this age group.
- No cases of myocarditis or pericarditis were reported in children in the pre-authorization clinical trials of Pfizer-BioNTech (ages 6 months–4 years) or Moderna (ages 6 months–5 years) vaccines.
- To date, post-authorization surveillance has not detected an increased risk for myocarditis and pericarditis following mRNA COVID-19 vaccination in children ages 6 months–4 years (Pfizer-BioNTech) and ages 6 months–5 years (Moderna).

Novavax COVID-19 Vaccine

Cases of myocarditis and pericarditis were identified in clinical trials of Novavax COVID-19 Vaccine and have also been reported during post-authorization use outside the United States. These findings suggest that an increased risk for these conditions might be present after receiving Novavax COVID-19 vaccine.

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COVID-19 vaccination and SARS-CoV-2 infection

People exposed to SARS-CoV-2

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

COVID-19 vaccines are not recommended for post-exposure prophylaxis. People should be informed that vaccination is to help prevent severe COVID-19 following future exposures.

People with prior or current SARS-CoV-2 infection

COVID-19 vaccination is recommended for everyone ages 6 months and older, regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection, including people with prolonged post-COVID-19 symptoms.

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

People who recently had SARS-CoV-2 infection may consider delaying a COVID-19 vaccine dose by 3 months from symptom onset or positive test (if infection was asymptomatic). Studies have shown that increased time between infection and vaccination might result in an improved immune response to vaccination. Also, a low risk of reinfection has been observed in the weeks to months following infection. Individual factors such as risk of COVID-19 severe disease or characteristics of the predominant SARS-CoV-2 strain should be taken into account when determining whether to delay getting a COVID-19 vaccination after infection.

Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection is not recommended for the purpose of vaccine decision-making.

People who received SARS-CoV-2 antibody-based products

People who previously received antibody products (anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment or post-exposure prophylaxis may be vaccinated at any time; COVID-19 vaccination does not need to be delayed following receipt of monoclonal antibodies or convalescent plasma. Although some reduction in vaccine-induced antibody titers was observed in people who previously received antibody products, the clinical significance of this reduction is unknown, and the balance of benefits vs. risks favors proceeding with vaccination even considering the possibility of diminished vaccine effectiveness in this situation. Those who received antibody products due to a recent SARS-CoV-2 infection should follow the guidance in the section above.

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

MIS-C is a rare but severe condition in children and adolescents infected with SARS-CoV-2. MIS-A, a similar condition in adults, is even rarer and less well characterized. Both include a dysregulated immune response to SARS-CoV-2 infection. There are limited data on the safety of COVID-19 vaccines in people who have had MIS-C or MIS-A (MIS C/A). The risk of recurrence of a dysregulated immune response following reinfection with SARS-CoV-2 or an MIS-like illness following COVID-19 vaccination is unknown.

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

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

Experts consider the benefits of COVID-19 vaccination for people with a history of MIS-C or MIS-A (i.e., a reduced risk of severe disease including potential recurrence of MIS-C after reinfection) to outweigh a theoretical risk of an MIS-like illness or the risk of myocarditis following COVID-19 vaccination for those who meet the following two 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; see also Consultation for decisions about COVID-19 vaccination. Experts view clinical recovery, including return to baseline cardiac function, as an important factor when considering COVID-19 vaccination. Additional factors, such as the risk of severe COVID-19 due to age or certain medical conditions, may also be considered.

Timing of COVID-19 vaccination

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

Considerations for people diagnosed with MIS-C or MIS-A after COVID-19 vaccination

Evaluation of people who develop MIS-C or MIS-A after COVID-19 vaccination

In the rare instance a person develops MIS-C, MIS-A, or a similar clinical illness after receipt of a COVID-19 vaccine, referral to specialists in infectious diseases, rheumatology, and/or cardiology should be considered.

- Assessment should include testing for current or prior SARS-CoV-2 infection, in addition to other potential etiologies as clinically indicated.
- Obtaining a serum sample before any intravenous immune globulin (IVIG) is administered is highly recommended so that the sample can be tested for SARS-CoV-2 anti-nucleocapsid antibody, which might require a reference laboratory.
    - A positive anti-nucleocapsid antibody test result indicates prior SARS-CoV-2 infection. (To test for current SARS-CoV-2 infection, a molecular diagnostic or antigen test should be used).
    - Anti-spike protein antibody testing cannot be used to determine SARS-CoV-2 infection status in a vaccinated person because a positive test result can be induced by either COVID-19 vaccination or SARS-CoV-2 infection.
- Treatment should not be delayed until test results are available.

Decisions about administration of subsequent COVID-19 vaccine doses in people who develop MIS-C or MIS-A after COVID-19 vaccination depend on timing of MIS in relation to vaccination, clinical recovery, and epidemiologic considerations.

Administration of subsequent COVID-19 vaccine doses: Onset of MIS 90 days or more after most recent COVID-19 vaccine dose

Administration of subsequent COVID-19 vaccine dose(s) should be considered for those who meet the two criteria listed below:

1. Clinical recovery has been achieved, including return to baseline cardiac function; and
2. It has been at least 90 days after the diagnosis of MIS-C or MIS-A

For people who had MIS-C or MIS-A but do not meet both criteria above, see Consultation for decisions about COVID-19 vaccination.

Administration of subsequent COVID-19 vaccine doses: Onset of MIS fewer than 90 days after most recent COVID-19 vaccine dose

Subsequent COVID-19 vaccine dose(s) should be deferred at this time until additional data are available. However, on a case-by-case basis, a provider may offer subsequent dose(s) if the two criteria above are met and there is strong evidence that the MIS-C or MIS-A was a complication of a recent SARS-CoV-2 infection.

Consultation for decisions about COVID-19 vaccination

A conversation between the patient and/or their guardian(s) and their clinical team or a specialist (e.g., infectious diseases, rheumatology, and/or cardiology) is strongly encouraged to assist with decisions about the use of COVID-19 vaccines in the setting of MIS-C or MIS-A.

For complicated situations, not addressed by the guidance above, healthcare and public health professionals may consider requesting a consultation from the Clinical Immunization Safety Assessment COVIDvax project. An illness consistent with MIS-C or MIS-A after receiving COVID-19 vaccine should be reported to VAERS .

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Considerations involving pregnancy, lactation, and fertility

Staying up to date with COVID-19 vaccinations is recommended for people who are pregnant, trying to get pregnant now, or who might become pregnant in the future, and people who are breastfeeding. A growing body of evidence on the safety and effectiveness of COVID-19 vaccination indicates that the benefits of vaccination outweigh any potential risks of COVID-19 vaccination during pregnancy.

Side effects can occur after COVID-19 vaccination in pregnant people, similar to those among non-pregnant people. Acetaminophen can be offered as an option for pregnant people experiencing fever (fever has been associated with adverse pregnancy outcomes) or other post-vaccination symptoms.

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Footnotes

1. For intervals of 3 months or less, 28 days (4 weeks) is a “month.” For intervals of 4 months or longer, a month is a “calendar month.” For age group ranges (e.g., 6 months–4 years, 5–11 years), a dash (–) should be read as “through” and the upper range includes that year through the last day before the birth date.
2. The Society of Breast Imaging (SBI) has developed Revised SBI Recommendations for the Management of Axillary Adenopathy in Patients with Recent COVID-19 Vaccination which includes considerations for patients and healthcare professionals in scheduling screening exams in relation to the administration of a COVID-19 vaccine.

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