



Vaccines & Immunizations

FAQs for the Interim Clinical Considerations for COVID-19 Vaccination

This page has answers to commonly asked questions about the Interim Clinical Considerations for COVID-19 Vaccination.

For information about COVID-19 vaccine storage, preparation, and administration, see U.S. COVID-19 Vaccine Product Information.

Vaccine Use and Schedule

Is there a preferred COVID-19 vaccine?

Yes, **bivalent** mRNA COVID-19 vaccines (Moderna or Pfizer-BioNTech) are recommended. The **monovalent** mRNA vaccines are no longer used in the United States.

Novavax COVID-19 Vaccine may also be used. Janssen COVID-19 Vaccine is no longer available or recommended in the United States.

For more information, see COVID-19 vaccines.

Are monovalent mRNA COVID-19 vaccines still recommended in the United States?

No, monovalent mRNA COVID-19 vaccines are no longer recommended in the United States; only bivalent mRNA vaccines (Moderna or Pfizer-BioNTech) are recommended.

Who is recommended to receive bivalent mRNA COVID-19 vaccine?

Everyone ages 6 months and older is recommended to receive bivalent mRNA COVID-19 vaccine. Most people need only 1 bivalent mRNA vaccine dose; the number of doses a person needs depends on their age, COVID-19 vaccination history, and immune status.

For information on the current COVID-19 vaccination schedule, see the vaccination schedule for people who are not immunocompromised and people who are moderately or severely immunocompromised.

Is an additional bivalent mRNA vaccine dose recommended for people ages 65 years and older?

People ages 65 years and older who previously received 1 dose of a bivalent mRNA vaccine have the option to receive 1 additional dose at least 4 months after the first bivalent dose.

Can people ages 65 years and older receive more than 1 dose of bivalent COVID-19 vaccine?

People ages 65 years and older are recommended to receive 1 dose of a bivalent mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech). They have the option to receive 1 additional vaccine dose, for a total of 2 bivalent vaccine doses, regardless of the number of previous monovalent vaccine doses received. The additional bivalent vaccine dose should be administered at least 4 months after the first bivalent vaccine dose.

For additional information, see the vaccination schedule for people who are not immunocompromised. For people ages 65 years and older who are moderately or severely immunocompromised, see the vaccination schedule for people who are moderately or severely immunocompromised.

What is the recommendation for administering a bivalent mRNA vaccine dose to people who previously received 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 dose of a bivalent mRNA vaccine. Either Moderna or Pfizer-BioNTech COVID-19 vaccine may be used.

For additional information see Novavax COVID-19 Vaccine.

What is the current guidance for use of the monovalent Novavax COVID-19 Vaccine?

Monovalent Novavax COVID-19 Vaccine is authorized for:

- Primary series vaccination: In people ages 12 years and older.
- Booster vaccination in limited situations as follows: In people ages 18 years and older who previously completed a
 monovalent primary series with any COVID-19 vaccine; have not received any previous booster dose(s); and are
 unable (i.e., vaccine is contraindicated or not available) or unwilling to receive an mRNA vaccine.

For additional information on the use of the vaccine and schedule, see Novavax COVID-19 Vaccine.

Does the 4-day grace period apply to COVID-19 vaccine?

Yes. Doses administered up to 4 days before the minimum interval, known as the 4-day grace period, are considered valid. Do not use the grace period to schedule doses.

If a dose is administered earlier than the grace period, see Appendix C for guidance on corrective actions. It is considered a vaccine administration error; you are required to report COVID-19 vaccine administration errors to the Vaccine Adverse Event Reporting System (VAERS) .

Doses administered at any time after the recommended interval are valid.

For information on dosing intervals for COVID-19 vaccines, see the vaccination schedule for people who are not immunocompromised and people who are moderately or severely immunocompromised.

In accordance with general best practices for immunizations, routine administration of all age-appropriate doses of vaccines simultaneously is recommended for children, adolescents, and adults for whom no specific contraindications exist at the time of the healthcare visit. This includes simultaneous administration of COVID-19 vaccine and other vaccines. However, there are additional considerations applicable to all COVID-19 vaccines if administering an orthopoxvirus (mpox) vaccine.

For more information, see Coadministration of COVID-19 vaccines with other vaccines.

Can COVID-19 vaccines be administered at the same time as an orthopoxvirus (mpox) vaccine?



- 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 more information, see:

- Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines during the 2022 U.S. Mpox Outbreak
- Coadministration of COVID-19 vaccines with other vaccines

Vaccine Dosage and Formulation

What should be done if a monovalent mRNA vaccine is administered instead of a bivalent mRNA vaccine?



If a monovalent mRNA vaccine is administered instead of a bivalent mRNA vaccine, the dose should be repeated with a bivalent mRNA vaccine. If it is the first bivalent dose, administer the repeat dose at least 28 days after the dose given in error. If it is a second or subsequent bivalent dose, administer the repeat dose by at least the minimum interval (see Table 1 and Table 2).

Are mRNA COVID-19 vaccines from different manufacturers (Moderna and Pfizer-BioNTech) interchangeable?



Use of mRNA COVID-19 vaccines interchangeably from different manufacturers (Moderna and Pfizer-BioNTech) varies by recipient age, vaccination history, and vaccine product:

- Ages 6 months-4 years: Children 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.
- Age 5 years: Children 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.

- Monovalent Pfizer-BioNTech COVID-19 are authorized to receive only bivalent Pfizer-BioNTech COVID-19 Vaccine.
- **Ages 6 years and older**: People 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.

For additional information, see Interchangeability of COVID-19 vaccines. The COVID-19 vaccination schedules for People who are not moderately or severely immunocompromised and People who are moderately or severely immunocompromised should be consulted for age-specific information; see also Appendix C for recommended actions following interchangeability-related errors or deviations in administration of COVID-19 vaccines.

How many doses of bivalent mRNA vaccine are recommended for children ages 6 months–5 years / initiating COVID-19 vaccination?

The number of doses of bivalent mRNA COVID-19 vaccine recommended for children initiating COVID-19 vaccination differs depending on age group and vaccine:

• Ages 6 month-4 years

o Moderna: 2 doses

o Pfizer-BioNTech: 3 doses

Age 5 years

Moderna: 2 doses

o Pfizer-BioNTech: 1 dose

For information on the schedule, including the dosage and interval between doses, see the COVID-19 vaccination schedule for people who are not moderately or severely immunocompromised.

For children ages 6 months–5 years initiating COVID-19 vaccination and who require more than 1 bivalent mRNA vaccine dose, should all doses be from the same manufacturer?

Children ages 6 months–5 years who are unvaccinated and are recommended to receive more than 1 bivalent mRNA vaccine dose for initial vaccination should receive all doses from the same manufacturer.

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

For information on the schedule, including the dosage and interval between doses, see the COVID-19 vaccination schedule for people who are not moderately or severely immunocompromised.

What is the recommendation for children ages 6 month–4 years who are initiating vaccination and \wedge received 2 doses of bivalent mRNA vaccine from different manufacturers (i.e., 1 Moderna and 1 Pfizer-BioNTech dose)?

Children ages 6 months–4 years who receive different bivalent mRNA vaccines for the first 2 doses of an mRNA COVID-19 vaccine series should follow a 3-dose schedule. A third dose of either mRNA vaccine (Moderna of Pfizer-BioNTech) should be administered at least 8 weeks after the second dose:

- If Moderna is used, administer 0.25 mL/25 ug (dark blue cap and label with gray border)
- If Pfizer-BioNTech is used, administer 0.2 mL/3 ug (maroon cap and label with maroon border)

For additional information, see Interchangeability of COVID-19 vaccines.

What is the recommendation for children ages 6 month–4 years who previously received 2 doses of monovalent mRNA vaccine from different manufacturers (i.e., 1 Moderna and 1 Pfizer-BioNTech dose)?

Children ages 6 months–4 years who previously received 2 doses of monovalent mRNA vaccine from different manufacturers (i.e., 1 Moderna and 1 Pfizer-BioNTech monovalent dose) should receive 1 dose of a bivalent mRNA vaccine from either manufacturer (Moderna or Pfizer-BioNTech). The bivalent vaccine dose should be administered at least 8 weeks after the last (i.e., second) monovalent dose:

- If Moderna is used, administer 0.25 mL/25 ug (dark blue cap and label with gray border)
- If Pfizer-BioNTech is used, administer 0.2 mL/3 ug (maroon cap and label with maroon border)

For additional information, see Interchangeability of COVID-19 vaccines.

There are two presentations of Moderna COVID-19 Vaccine (pink cap and label with yellow line; dark blue cap and label with gray border): when should each be used?

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The two presentations of Moderna COVID-19 Vaccine and recommended dosages are as follows:

- Pink cap and label with yellow line (0.2 mL/10 μg)
- Dark blue cap and label with gray border (25 mL/25 μg; 0.5 mL/50 μg)

The presentation and dosage are determined by the recipient's age, vaccination history, and the presence of moderate or severe immune compromise; for patient-specific guidance see:

- Moderna Bivalent Vaccine Vial Infographic
- Vaccination schedule for people who are not immunocompromised
- Vaccination schedule for people who are moderately or severely immunocompromised

What should be done if the incorrect vaccine formulation is administered based on a patient's age?

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If the incorrect formulation is administered:

- Resulting in a higher-than-authorized dose: Do not repeat dose.
- Resulting in a lower-than-authorized dose: Repeat the dose immediately (no minimum interval) with the ageappropriate dose and formulation. Some experts suggest delaying the repeat dose for 8 weeks after the invalid dose based on the potential for increased reactogenicity and the rare risk of myocarditis and pericarditis associated with Moderna, Novavax, and Pfizer-BioNTech vaccines, especially in males ages 12–39 years. See Considerations for extended intervals for COVID-19 vaccine primary series.

For more information, see:

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

• COVID-19 vaccination schedule for people who are not immunocompromised and people who are moderately or severely immunocompromised

Age Transitions

What vaccine product and dosage should be used for a person who is moving from a younger age ____ group with a lower dose formulation to an older age group with a higher dose formulation?

In general, CDC recommends that people receive the age-appropriate vaccine dosage based on their age on the day of vaccination. If a person moves from a younger age group 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 described in the following two FAQs in this section.

What is the guidance for children who transition from age 4 years to 5 years during the 3-dose Pfizer-BioNTech COVID-19 vaccination series?

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Children who transition from age 4 years to 5 years during the 3-dose bivalent Pfizer-BioNTech COVID-19 vaccination series must complete the series they start (i.e., receive the 0.2 mL/3 ug dosage supplied in vials with a maroon cap and label with a maroon border for all 3 doses).

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.

For additional information, see:

- Timing, spacing, age transitions, and coadministration of COVID-19 vaccines
- COVID-19 vaccination schedule for people who are not immunocompromised and people who are moderately or severely immunocompromised

What is the guidance for children who transition from age 5 years to 6 years during the 2-dose Moderna COVID-19 vaccination series?



Children who transition from age 5 years to 6 years during the 2-dose bivalent Moderna COVID-19 vaccination series should receive 2 doses of Moderna (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.

For additional information, see:

- Timing, spacing, age transitions, and coadministration of COVID-19 vaccines
- COVID-19 vaccination schedule for people who are not immunocompromised and people who are moderately or severely immunocompromised

Are there special considerations for vaccinating people who are moderately or severely immunocompromised?

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Yes. For COVID-19 vaccination guidance for people who are moderately or severely immunocompromised, see Guidance for COVID-19 vaccination for people who are moderately or severely immunocompromised.

Can people who are moderately or severely immunocompromised receive additional doses of bivalent mRNA vaccine?

Yes, people who are moderately or severely immunocompromised have the option to receive 1 additional dose of an age-appropriate bivalent mRNA vaccine at least 2 months following the last recommended bivalent COVID-19 vaccine dose. Further additional dose(s) of bivalent mRNA vaccine 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.

The vaccine (Moderna or Pfizer-BioNTech) and dosage for the additional doses depend on age and vaccination history (i.e., whether Moderna or Pfizer-BioNTech was received for the initial bivalent mRNA doses).

For additional information, see the COVID-19 vaccination schedule for people who are moderately or severely immunocompromised.

Which vaccine (Moderna or Pfizer-BioNTech) should be administered to people who are moderately or severely immunocompromised for their additional doses?



For people who are moderately or severely immunocompromised, the vaccine (Moderna or Pfizer-BioNTech) for the additional doses depends on the age and whether they received Pfizer or Moderna for their initial bivalent mRNA dose(s).

• Age 6 months-4 years

- o Previously received Moderna: Only Moderna
- o Previously received Pfizer-BioNTech: Only Pfizer-BioNTech

Age 5 years

- Previously received Moderna: Either Moderna or Pfizer-BioNTech
- Previously received Pfizer-BioNTech: Only Pfizer-BioNTech

• Age 6 years and older

o Either Moderna or Pfizer-BioNTech regardless of which vaccine was received for their initial bivalent doses

For children ages 6 months–4 years or age 5 years who are moderately or severely immunocompromised and receiving Moderna COVID-19 Vaccine for their additional doses, which Moderna formulation should be used?

For children ages 6 months–4 years or age 5 years who are moderately or severely immunocompromised and receiving Moderna COVID-19 Vaccine for their additional doses, Moderna 0.2mL/10 ug (dark pink cap and label with a yellow boarder) is recommended. However, Moderna 0.25 mL/25 ug (dark blue cap and label with a gray border) is also authorized and it is not an error to administer this dosage. For additional information, see COVID-19 vaccination schedule

How do I verify if a person is moderately or severely immunocompromised?

People can self-attest to their moderately or severely immunocompromised status and should be vaccinated according to the schedule for people who are moderately or severely immunocompromised. Health care professionals, vaccinators and clinic administrators should not deny COVID-19 vaccination to a person because of a lack of documentation.

Should people who undergo hematopoietic cell transplant (HCT) or chimeric antigen receptor (CAR)-T cell therapy be revaccinated?

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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 after treatment and follow the currently recommended schedule for people who are unvaccinated.

For additional information, see:

- Considerations for COVID-19 revaccination
- COVID-19 vaccination schedule for people who are moderately or severely immunocompromised.

My patient is moderately or severely immunocompromised and previously received EVUSHELD™(tixagevimab/cilgavimab). Should they be vaccinated against COVID-19?



Yes. Everyone ages 6 months and older is recommend to be vaccinated against COVID-19, including people who are moderately or severely immunocompromised and who previously received EVUSHELD™ for pre-exposure prophylaxis.

COVID-19 vaccines can be administered any time after receipt of EVUSHELD™.

For additional information, see the COVID-19 vaccination schedule for people who are moderately or severely immunocompromised.

Vaccination and SARS-CoV-2 Laboratory Testing

What do antibody tests tell us about immunity, and should these tests influence the decision to vaccinate or revaccinate?



Antibody testing is **not** currently recommended to assess the need for vaccination in an unvaccinated person or to assess immunity to SARS-CoV-2 following COVID-19 vaccination or after SARS-CoV-2 infection. Antibody tests for SARS-CoV-2 look for the presence of antibodies made in response to a previous infection or vaccination. Antibodies are an indicator of the body's efforts to fight off the SARS-CoV-2 virus. None of the currently authorized SARS-CoV-2 antibody tests \square have been validated to assess specific immunity or protection from SARS-CoV-2 infection or vaccination.

For additional information, see:

- Interim Guidelines for COVID-19 Antibody Testing
- COVID-19 Testing: What you Need to Know
- Antibody (Serology) Testing for COVID-19: Information for Patients and Consumers 🖸

Vaccination and SARS-CoV-2 Infection

Can people with prior or current SARS-CoV-2 infection receive a COVID-19 vaccine?

CDC recommends COVID-19 vaccination for all people ages 6 months and older, including people with a history of SARS-CoV-2 infection.

Prior infection: Offer vaccination regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection, including to people with prolonged post-COVID-19 symptoms and people who experienced SARS-CoV-2 infection (symptomatic or asymptomatic) after vaccination. People who recently had SARS-CoV-2 infection may consider delaying their COVID-19 vaccine dose by 3 months from symptom onset or positive test (if infection was asymptomatic).

Current infection: Defer vaccination of people with known current SARS-CoV-2 infection until the person has recovered from acute illness (if the person has symptoms) and until criteria have been met for them to discontinue isolation.

Laboratory testing is not recommended for the purpose of vaccine decision-making.

For more information, see COVID-19 vaccination and SARS-CoV-2 infection.

Special Populations and Situations

Can pregnant or breastfeeding people be vaccinated?

Yes. CDC recommends COVID-19 vaccination for all people who are pregnant, breastfeeding, recently pregnant, trying to get pregnant now, or who might become pregnant in the future. mRNA vaccines are recommended for all vaccine-eligible populations including people who are pregnant or lactating.

For more information, see COVID-19 Vaccines While Pregnant or Breastfeeding.

What is the guidance for vaccinating preterm infants?

In accordance with general best practices, preterm infants (infants born before 37 weeks' gestation), regardless of birth weight, should receive COVID-19 vaccination at their chronological age and according to the same schedule and guidance as for full-term infants and children.

What is the guidance for vaccinating infants of mothers who received COVID-19 vaccine and/or had COVID-19 or SARS-CoV-2 infection before or during pregnancy?

Infants of mothers who were vaccinated and/or had COVID-19 or SARS-CoV-2 infection before or during pregnancy should be vaccinated according to the recommended schedule.

If my patient received a SARS-CoV-2 antibody product (anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma) can they be vaccinated?

People who previously received SARS-CoV-2 antibody products (anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment, post-exposure prophylaxis, or pre-exposure prophylaxis can be vaccinated at any time; COVID-19 vaccination does not need to be delayed following receipt of monoclonal antibodies or convalescent plasma.

Which COVID-19 vaccines are recommended for people with a history of Bell's palsy?

Rare cases of Bell's palsy (acute peripheral facial nerve palsy) were reported following vaccination of participants in mRNA COVID-19 vaccine clinical trials, but FDA was not able to determine whether these cases were causally related to vaccination. People with a history of Bell's palsy may receive any currently FDA-authorized COVID-19 vaccine, though mRNA vaccines (Moderna or Pfizer-BioNTech) are recommended.

For additional information, see the COVID-19 vaccination schedule for people who are not immunocompromised and people who are moderately or severely immunocompromised.

Which COVID-19 vaccines are recommended for people with a history of Guillain-Barré syndrome (GBS)?

For people with a history of GBS, there is no contraindication to administering an mRNA (Moderna or Pfizer-BioNTech) or Novavax COVID-19 vaccine. No increased risk of GBS has been identified with receipt of mRNA COVID-19 vaccines.

For additional information, see the COVID-19 vaccination schedule for people who are not immunocompromised and people who are moderately or severely immunocompromised.

Last Reviewed: June 14, 2023