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Vaccines & Immunizations

CDC now recommends that children between the ages of 5 and 11 years receive the Pfizer-BioNTech pediatric COVID-19 Vaccine. Get more information and read CDC's media statement.

Reference Materials

- Summary Document for Interim Clinical Considerations
- Summary Document for Interim Clinical Considerations poster
- COVID-19 Vaccine Administration Errors and Deviations
- COVID-19 Vaccine Administration Errors and Deviations Poster
- Presentation: Clinical Care Consideration Slides for Healthcare Providers

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Summary of recent changes (last updated November 3, 2021):

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

Key points

- COVID-19 vaccination is recommended for everyone aged 5 years and older in the United States for the prevention of coronavirus disease 2019 (COVID-19).
- COVID-19 vaccines currently approved or authorized by FDA are effective in preventing serious outcomes of COVID-19, including severe disease, hospitalization, and death.
- Efforts to maximize the proportion of people in the United States who are fully vaccinated against COVID-19 remain critical to ending the COVID-19 pandemic.

- The Advisory Committee on Immunization Practices (ACIP) and CDC have issued interim recommendations for the use of three COVID-19 vaccines:
  - Pfizer-BioNTech COVID-19 Vaccine/COMIRNATY
  - Moderna COVID-19 Vaccine
  - Janssen (Johnson & Johnson) COVID-19 Vaccine
- ACIP and CDC consider individual and public health benefits and risks along with factors such as population values, acceptability, and feasibility of implementation when making vaccine recommendations.
- These clinical considerations provide additional information to healthcare professionals and public health officials on use of COVID-19 vaccines.

Purpose

The Centers for Disease Control and Prevention (CDC) Interim Clinical Considerations provides additional information to healthcare professionals and public health officials on the use of COVID-19 vaccines. They are informed by the Advisory Committee on Immunization Practices (ACIP) and CDC's recommendations, data submitted to the U.S. Food and Drug Administration (FDA) for Biologics License Application (BLA) or Emergency Use Authorization (EUA) of the vaccines, other data sources, including the World Health Organization (WHO) emergency use listing (EUL) evaluation of COVID-19 vaccines and clinical trial results, general best practice guidelines for immunization, and expert opinion. These considerations apply only to the use of vaccine products currently approved or authorized in the United States. These considerations will be updated when additional information becomes available or if additional vaccine products are approved or authorized.

In addition to the following considerations, the BLA or EUA conditions of use and storage, handling, and administration procedures described in the prescribing information should be consulted when using the Pfizer-BioNTech □ , Moderna □ , and Janssen □ COVID-19 vaccines.

Overview of COVID-19 vaccine recommendations

COVID-19 vaccines approved or authorized by the Food and Drug Administration

Three COVID-19 vaccines are currently approved under a BLA or authorized under an EUA by FDA:

- Pfizer-BioNTech COVID-19 Vaccine/COMIRNATY[1]
- Moderna COVID-19 Vaccine

- Janssen (Johnson & Johnson) COVID-19 Vaccine

Regulatory terminology for COVID-19 vaccines

Emergency Use Authorization (EUA): mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. Under an EUA, the U.S. Food and Drug Administration (FDA) can make a product available to the public based on the best available evidence, without waiting for all the evidence that would be needed for FDA approval.

FDA Approved : FDA-approved vaccines have undergone the agency's standard process for reviewing the quality, safety and effectiveness of medical products included in a manufacturer's submission of a **Biologics License Application (BLA)**—a comprehensive document that addresses specific requirements.

COVID-19 vaccine recommendations

COVID-19 vaccination is recommended for everyone aged 5 years and older in the United States for the prevention of COVID-19. However, the age groups approved under BLA or authorized under EUA to receive vaccination vary by vaccine product. CDC has issued recommendations for primary series, additional primary doses, and booster doses of COVID-19 vaccines, as defined below.

Terminology for COVID-19 vaccine dosing

Primary series: 2-dose series of an mRNA COVID-19 vaccine (Pfizer-BioNTech and Moderna) or a single dose of Janssen vaccine

Additional primary dose: a subsequent dose of vaccine administered to people who likely did not mount a protective immune response after initial vaccination. An additional primary mRNA COVID-19 vaccine dose is recommended for moderately and severely immunocompromised people who received a 2-dose mRNA vaccine primary series.

Booster dose: a subsequent dose of vaccine administered to enhance or restore protection by the primary vaccination which might have waned over time.

Homologous booster dose: a subsequent dose of vaccine that is the same product as the primary series

Heterologous booster dose (mix-and-match booster): a subsequent dose of vaccine that is a different product than the primary series

The following groups are recommended to receive COVID-19 vaccine:

Primary series

- Pfizer-BioNTech: a 2-dose primary series
  - 10 µg dose formulation in persons aged 5–11 years
  - 30 µg dose formulation in persons aged ≥12 years
- Moderna: a 2-dose primary series in persons aged ≥18 years
- Janssen: a single dose primary series in persons aged ≥18 years

Additional dose for moderately and severely immunocompromised people is recommended ≥28 days after completion of a 2-dose mRNA primary series

- Pfizer-BioNTech: persons aged ≥12 years
- Moderna: persons aged ≥18 years

Janssen COVID-19 Vaccine is not authorized for use as an additional primary dose.

After completion of a 2-dose mRNA primary series and an additional primary mRNA vaccine dose, moderately and severely immunocompromised people are eligible to receive a booster dose as described below. Moderately and severely immunocompromised people who received a single dose Janssen COVID-19 primary series are recommended to receive a booster dose.

Currently, CDC does not recommend an additional primary dose in children aged 5–11 years. As more data become available, this recommendation may be updated.

Booster dose

Any of the COVID-19 vaccines can be used for booster vaccination, regardless of the vaccine product used for primary vaccination. When a heterologous or "mix and match" booster dose is administered, the eligible population and dosing intervals are those of the vaccine used for primary vaccination.

mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) recipients

The following recipients of an mRNA primary series **should** receive a single COVID-19 booster dose (Pfizer-BioNTech, Moderna, or Janssen) at least 6 months after completion of the primary series:

- People aged 65 years and older
- Residents aged 18 years and older in long-term care settings
- People aged 50–64 years with certain underlying medical conditions

The following recipients of an mRNA primary series **may** receive a single COVID-19 booster dose (Pfizer-BioNTech, Moderna, or Janssen) at least 6 months after completing their primary series based on their individual benefits and risks:

- People aged 18–49 years with certain underlying medical conditions
- People aged 18–64 years at increased risk for SARS-CoV-2 exposure and transmission because of occupational or institutional setting

These additional primary dose and booster dose recommendations also apply to people who received two doses of different mRNA COVID-19 vaccine products for their primary series.

Moderately and severely immunocompromised people aged ≥18 years who received a 2-dose mRNA primary series and an additional primary dose (3 total mRNA COVID-19 vaccine doses) are eligible for a single COVID-19 booster dose (Pfizer-BioNTech, Moderna, or Janssen) at least 6 months after completing their third mRNA vaccine dose.

Janssen COVID-19 Vaccine recipients

- People aged ≥18 years who received a single dose Janssen primary series **should** receive a single COVID-19 booster dose (Pfizer-BioNTech, Moderna, or Janssen) at least 2 months (8 weeks) after completing their Janssen primary series.

Currently, CDC does not recommend a booster dose in children aged 5–17 years. As more data become available, this recommendation may be updated.

There is currently no FDA-approved or FDA-authorized COVID-19 vaccine for children aged <5 years. Ongoing clinical trials of COVID-19 vaccine in children aged <5 years are examining a range of vaccine doses that are lower than the standard dose prescribed for people aged ≥5 years. Data from these trials will be used to determine the optimal dose to protect children aged <5 years while minimizing potential adverse events. **Children aged <5 years should not receive any COVID-19 vaccine doses (either standard or partial doses) at this time unless part of a clinical trial.**

COVID-19 vaccine dosing and schedule

Vaccine product information for administration, storage and handling, safety, and reporting procedures is available, including product-specific information for Pfizer-BioNTech, Moderna, and Janssen.

Dosing

Primary series

Primary and additional primary doses vaccine manufacturer	Age of recipient (years)	Vial cap color denoting formulation	Concentration of mRNA per primary dose	Primary dosage injection volume	Number of doses in primary series (interval between doses)	Additional primary dose in immunocompromised people (interval since second dose)	Interval between last primary (including additional) to booster dose
Pfizer-BioNTech	5–11	Orange	10 µg	0.2 ml	2 (21 days)	Not recommended	Booster not recommended
Pfizer-BioNTech	12–17	Purple	30 µg	0.3 ml	2 (21 days)	1 (≥28 days)	Booster not recommended
Pfizer-BioNTech	≥18	Purple	30 µg	0.3 ml	2 (21 days)	1 (≥28 days)	≥6 months
Moderna	≥18	Not applicable	100 µg	0.5 ml	2 (28 days)	1 (≥28 days)	≥6 months
Janssen	≥18	Not applicable	5×10^{10} viral particles	0.5 ml	1 (Not applicable)	Not applicable	≥2 months

COVID-19 vaccines are administered intramuscularly. A single COVID-19 vaccine primary series (i.e., either a 2-dose mRNA COVID-19 vaccine series or a single dose of Janssen COVID-19 Vaccine) should be administered. It is not recommended to receive more than one complete COVID-19 primary series, with the exception of recipients of a hematopoietic cell transplant (HCT) or chimeric antigen receptor (CAR)-T-cell therapy.

Prior to administration, vaccination providers should ensure the age-appropriate formulation is administered. Pfizer-BioNTech COVID-19 Vaccine is supplied as two different dosage formulations distinguished by different colored vial caps:

- The Pfizer-BioNTech 10 µg formulation (orange cap) is FDA-authorized for use in children aged 5–11 years for primary vaccination. This formulation uses a tris-sucrose buffer to enable lower concentrations of mRNA for 10 µg dosing. **Only the 10 µg tris-sucrose buffer formulation (orange cap) is authorized for use in children aged 5–11 years.**
- The Pfizer-BioNTech 30 µg formulation (purple cap) is FDA-approved for use in persons aged ≥16 years and FDA-authorized for use in persons aged 12–15 years. This formulation should be used for the primary series, additional primary dose (for persons aged ≥12 years), and booster dose (for persons aged ≥18 years). This formulation uses phosphate buffered saline (PBS).

A person is considered fully vaccinated against COVID-19 ≥2 weeks after receipt of the second dose in a 2-dose series (Pfizer-BioNTech and Moderna) or ≥2 weeks after receipt of the single dose of the Janssen

Vaccine. CDC has developed interim public health recommendations for fully vaccinated people. Administration of an additional primary dose or a booster dose is not required to be considered fully vaccinated for public health purposes at this time. People who have a contraindication to vaccination or who otherwise do not complete a primary vaccination series are not considered fully vaccinated. People who have received an additional primary dose or a booster dose should continue to follow guidance for fully vaccinated persons to minimize spread of SARS-CoV-2 to others at this time.

Additional primary dose

Moderately and severely immunocompromised persons aged ≥12 years (Pfizer-BioNTech recipients) or ≥18 years (Moderna recipients) should receive an additional primary dose of the same mRNA COVID-19 vaccine administered for the primary series, as follows:

- Pfizer-BioNTech: 30 µg in a volume of 0.3 ml (same as the primary series dose and booster dose) for persons aged ≥12 years.
- Moderna: 100 µg in a volume of 0.5 ml (same as the primary series dose) for persons aged ≥18 years.

As more data become available, this recommendation may be updated to include younger age groups.

Booster dose

Booster dose vaccine manufacturer	Age of recipient (years)	Vial cap color denoting formulation	Booster dose	Booster dose injection volume	Number of doses
Pfizer-BioNTech	≥18	Purple	30 µg	0.3 ml	1
Moderna	≥18	Not applicable	50 µg*	0.25 ml	1
Janssen	≥18	Not applicable	5×10^{10} viral particles	0.5 ml	1

The booster dose and volume are the same, regardless of whether the vaccine is homologous (same dose as primary series) or heterologous (different than primary series).

- Pfizer-BioNTech: 30 µg in a volume of 0.3 ml (same dose as the primary series dose and additional primary dose).
- *Moderna: 50 µg in a volume of 0.25 ml. **This is a different dose than what is used for the primary series dose and the additional primary dose.**
- Janssen: 5×10^{10} viral particles in a volume of 0.5ml (same dose as the primary series dose).

Intervals between vaccine dose[2]

Primary series

Individuals who receive the second dose of an mRNA COVID-19 vaccine no more than 4 days before (referred to as the "grace period") or at any time after the recommended second dose date are considered to have completed the primary series.[3] If the second dose of an mRNA vaccine is given earlier than the 4-day grace period (i.e., the second dose is administered <17 days [Pfizer-BioNTech] or <24 days [Moderna]), the second dose **should** be repeated. The repeat dose should be spaced based on the date of the dose given in error by the recommended minimum interval (see Appendix A for more details).

Additional dose

The additional primary dose (i.e., third dose) of an mRNA COVID-19 vaccine should be administered at least 28 days after completion of the initial 2-dose mRNA COVID-19 primary series (see Considerations for COVID-19 vaccination in moderately and severely immunocompromised people).[3] If the additional primary dose of an mRNA COVID-19 vaccine is given fewer than 24 days after the second dose (i.e., administered earlier than the 4-day grace period), the additional primary dose **should** be repeated. The repeat dose should be spaced from the date of the dose given in error by the recommended minimum interval (see Appendix A for more details).

Booster dose

If a heterologous vaccine product is used for the booster dose, the interval should follow the interval recommended by the primary series; e.g., people who received a single dose Janssen primary series can receive an mRNA COVID-19 vaccine booster dose at least 2 months (8 weeks) after completing their Janssen primary series. In people eligible to receive an mRNA or Janssen COVID-19 booster dose, if the booster dose is given earlier than the 4-day grace period (i.e., administered more than 4 days before 6 months after a second mRNA primary vaccine dose or 4 days before 2 months [or more than 4 days before 8 weeks] after a Janssen primary vaccine dose), the booster dose does **not** need to be repeated.

Vaccine administration errors and deviations

Information on preventing, reporting, and managing COVID-19 vaccine administration errors is found in Appendix A. Vaccine administration errors should be reported to the Vaccine Adverse Event Reporting System (VAERS) .

Interchangeability of COVID-19 vaccine products

Any currently FDA-approved or FDA-authorized COVID-19 vaccine can be used when indicated; ACIP and CDC do not state a product preference. In general, primary series and additional primary doses should be with the same vaccine product (i.e., the same manufacturer and same formulation). However, use of

heterologous booster doses, as discussed below, is authorized.

mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna): primary series and additional primary doses

All doses of the primary series and the additional primary dose (for moderately and severely immunocompromised people) if indicated, should be completed with the same vaccine product. Various strategies can help ensure that people receive the appropriate product and interval between doses.

For people aged ≥18 years, in exceptional situations in which the mRNA vaccine product given for the first dose of the primary series cannot be determined or is not available, any available mRNA COVID-19 vaccine product may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series. In situations where the same mRNA vaccine product is temporarily unavailable, it is preferable to delay the second dose to receive the same product than to receive a mixed primary series using a different product. If two doses of different mRNA COVID-19 vaccine products are administered in these situations (or administered inadvertently), the primary series is considered complete, and no subsequent doses of either product are recommended to complete the primary series. Such persons are considered fully vaccinated against COVID-19 ≥2 weeks after receipt of the second dose of an mRNA vaccine and may be offered an additional primary dose or booster dose, if indicated.

The Pfizer-BioNTech COVID-19 Vaccine formulation (10 µg in 0.2 ml) with an orange cap vial should only be used for children aged 5–11 years. The Pfizer-BioNTech COVID-19 Vaccine (30 µg in 0.3 ml) with a purple cap vial should only be used for people aged ≥12 years. See additional information on vaccine administration errors and deviations in Appendix A.

Janssen Vaccine: primary series

In limited, exceptional situations where an individual received the first dose of an mRNA COVID-19 vaccine but is unable to complete the series with either the same or different mRNA COVID-19 vaccine (e.g., due to contraindication), a single dose of Janssen COVID-19 Vaccine may be considered at a minimum interval of 28 days from the mRNA COVID-19 vaccine dose if the person is aged ≥18 years. See the Contraindications and Precautions section for additional information on use of Janssen COVID-19 Vaccine and additional precautions in people with a contraindication to mRNA COVID-19 vaccines. People who receive Janssen COVID-19 Vaccine after a dose of an mRNA COVID-19 vaccine should be considered to have received a valid, single-dose Janssen vaccination—not a mixed primary vaccination series—and are considered fully vaccinated against COVID-19 ≥2 weeks after receipt of the single dose of the Janssen Vaccine.

Interchangeability of booster doses

Heterologous (mix and match) booster doses can be used in eligible recipients aged ≥18 years (see Considerations for use of a COVID-19 vaccine booster dose for more details).

People who received COVID-19 vaccine outside the United States

People who were vaccinated outside the United States with a currently FDA-approved or FDA-authorized COVID-19 vaccine or a WHO-EUL COVID-19 vaccine[4] and who have received all the recommended doses are considered fully vaccinated and **do not need** any subsequent primary series doses.

People who received the first dose of a 2-dose FDA-approved or FDA-authorized mRNA COVID-19 vaccine **do not need to restart** the vaccine series in the United States. They should receive the second dose as close to the recommended time as possible and are considered fully vaccinated upon completion of the 2-dose primary series.

People who were vaccinated in countries where only a single mRNA COVID-19 vaccine dose is administered are not considered fully vaccinated in the United States. They should be offered an age-appropriate second dose of an mRNA vaccine (i.e., Pfizer-BioNTech COVID-19 Vaccine formulation for persons aged 5–11 years [orange cap]; COMIRNATY; Pfizer-BioNTech COVID-19 formulation for persons ≥12 years old [purple cap]; or Moderna for persons ≥18 years) to complete the 2-dose primary series.

People who completed a primary vaccine series outside the United States and received FDA-approved, FDA-authorized, or WHO-EUL[4] COVID-19 vaccines as a mixed dose regimen are considered fully vaccinated as per CDC guidance. They do not need to restart a COVID-19 vaccine primary series in the United States. **This does not imply that these non-U.S. vaccine primary series regimens are approved or authorized by FDA or are recommended by CDC or ACIP**.

The following people who received a COVID-19 vaccine that is **not** currently FDA-approved or FDA-authorized in the United States may be offered a complete FDA-approved or FDA-authorized COVID-19 vaccine primary series as follows:

- People who have received only the first dose of a 2-dose COVID-19 primary series listed for emergency use by WHO[4]
- People who received all or some of the recommended doses of a COVID-19 vaccine primary series that is not listed for emergency use by WHO.

The minimum interval between receipt of the non-FDA-approved/authorized vaccine and initiation of the FDA-approved/authorized COVID-19 vaccine primary series is at least 28 days.

People vaccinated outside the United States: administration of a COVID-19 vaccine booster dose or additional primary dose

People who were vaccinated outside the United States and completed a primary vaccination series comprised of an FDA-authorized or FDA-approved COVID-19 vaccine (i.e., a single dose Janssen Vaccine or a 2-dose mRNA vaccine [including a mixed mRNA primary series]) may receive a booster dose (Pfizer-BioNTech, Moderna, or Janssen) if they are eligible. Considerations for use of a COVID-19 booster dose can be consulted for more information.

People who have completed a 2-dose mRNA COVID-19 vaccine (including a mixed mRNA primary series) may receive an additional mRNA dose (Pfizer-BioNTech or Moderna) at least 28 days after receiving the second mRNA vaccine dose if they are moderately or severely immunocompromised. Considerations for COVID-19 vaccination in moderately and severely immunocompromised people can be consulted for more information.

At this time, CDC has no recommendation regarding an additional primary dose or a booster dose for people who were vaccinated outside the United States with a WHO-EUL COVID-19 vaccine that is not FDA-authorized or approved.

People who received COVID-19 vaccine as part of a clinical trial in the United States

Some people in the United States have completed a COVID-19 vaccination series as part of a clinical trial with sites in the United States involving a COVID-19 vaccine that is currently neither approved nor authorized by FDA.

People who participated in a clinical trial in the United States and received the full series of a COVID-19 vaccine that is neither approved nor authorized by FDA but is listed for emergency use by WHO[4]

Clinical trial participants from U.S. sites who received all recommended doses of a COVID-19 vaccine that is neither approved nor authorized for use by FDA, but is listed for emergency use by WHO, do not need any further doses of an FDA-approved or FDA-authorized COVID-19 vaccine. Once it has been confirmed that a U.S. participant in a COVID-19 vaccine trial received "active" vaccine, and not placebo, the participant can be considered fully vaccinated 2 weeks after they completed the vaccine series. Currently, the AstraZeneca COVID-19 vaccine meets these criteria.

People who participated in a clinical trial in the United States and received the full series of a COVID-19 vaccine candidate that is neither approved nor authorized by FDA, nor listed for emergency use by WHO[4]

If a clinical trial participant from a U.S. site has been documented to have received the full series of an

"active" (not placebo) COVID-19 vaccine candidate, and vaccine efficacy has been independently confirmed (e.g., by a data and safety monitoring board), the participant can be considered fully vaccinated 2 weeks after they completed the vaccine series; clinical trial participants from sites outside the United States can be considered fully vaccinated if they received the same product that was administered and independently evaluated in the U.S. clinical trials. Currently, the Novavax COVID-19 vaccine meets these criteria. **This does not imply that the vaccine has been approved or authorized by FDA or is recommended by CDC or ACIP.**

Novavax clinical trial participants who did not receive the full 2-dose series of the active COVID-19 vaccine candidate should follow current prevention measures to protect themselves against COVID-19 and be offered an FDA-approved or FDA-authorized COVID-19 vaccine series.

Coadministration of COVID-19 vaccines with other vaccines

COVID-19 vaccines **may be administered without regard to timing of other vaccines**. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day.

If multiple vaccines are administered at a single visit, administer each injection in a different injection site. For people ≥11 years, the deltoid muscle can be used for more than one intramuscular injection administered at different sites in the muscle. For children (5–10 years), if more than two vaccines are injected in a single limb, the vastus lateralis muscle of the anterolateral thigh is the preferred site because of greater muscle mass.

Best practices for multiple injections include:

- Label each syringe with the name and the dosage (amount) of the vaccine, lot number, the initials of the preparer, and the exact beyond-use time, if applicable.
- Separate injection sites by 1 inch or more, if possible.
- **Administer the COVID-19 vaccines and vaccines that may be more likely to cause a local reaction in different limbs, if possible.**

See general best practices and Epidemiology and Prevention of Vaccine-Preventable Diseases (The Pink Book) for further information.

COVID-19 vaccination and SARS-CoV-2 infection

People with prior or current SARS-CoV-2 infection

COVID-19 vaccination is recommended for everyone aged 5 years and older, regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection; this includes people with prolonged post-COVID-19 symptoms and applies to primary series doses, additional primary doses, and booster doses. 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. Present data are insufficient to determine an antibody titer threshold that indicates when an individual is protected from SARS-CoV-2 infection. There is neither any FDA-authorized or FDA-approved test nor any other scientifically validated strategy that vaccination providers or the public can use to reliably determine whether a person is protected from infection.

Data from multiple studies indicate that the currently approved or authorized COVID-19 vaccines can be given safely to people with evidence of a prior SARS-CoV-2 infection. Current evidence suggests that the risk of SARS-CoV-2 reinfection is low after a previous infection but may increase with time due to waning immunity. Among individuals infected with SARS-CoV-2, substantial heterogeneity exists in their immune response. Conversely, the immune response following COVID-19 vaccination is more reliable, consistent, and predictable. A primary vaccination series decreases the risk of future infections in people with prior SARS-CoV-2 infection. Numerous immunologic studies have consistently shown that vaccination of individuals who were previously infected enhances their immune response, and growing epidemiologic evidence indicates that vaccination following infection further reduces the risk of subsequent infection, including in the setting of increased circulation of more infectious variants.

People with known current SARS-CoV-2 infection should defer vaccination at least until recovery from the acute illness (if symptoms were present) has been achieved and criteria to discontinue isolation have been met. Current evidence about the optimal timing between SARS-CoV-2 infection and vaccination is insufficient to inform guidance. This recommendation for vaccination applies to people who experience SARS-CoV-2 infection before receiving any vaccine dose and those who experience SARS-CoV-2 infection after the first dose of a COVID-19 vaccine, but before receipt of subsequent doses.

People with a history of multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A)

Multisystem inflammatory syndrome in children (MIS-C) is a rare but severe condition in children and adolescents infected with SARS-CoV-2. Multisystem inflammatory syndrome in adults (MIS-A) appears to be even rarer and is less well characterized than in children. The mechanisms of MIS-C and MIS-A are not well understood but include a dysregulated immune response to SARS-CoV-2 infection. The risk of recurrence of the same dysregulated immune response following reinfection with SARS-CoV-2 among people with a history of MIS-C or MIS-A is unknown. It is also unknown if some persons with a history of MIS-C or MIS-A may be at risk for an MIS-like illness following vaccination with COVID-19 vaccine.

Children with MIS-C have high antibody titers to SARS-CoV-2 □ , however, it is unknown if this correlates with protection against reinfection and for how long protective antibody levels persist.

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

Given the widespread transmission of SARS-CoV-2 across the United States and increases in hospitalizations of children and adolescents, several experts consider the benefits of COVID-19 vaccination for children and adolescents (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 risks of myocarditis following COVID-19 vaccination for people who meet all of the following criteria:

1. Clinical recovery has been achieved, including return to normal cardiac function;
2. It has been ≥90 days since their diagnosis of MIS-C;
3. They are in an area of high or substantial community transmission of SARS-CoV-2 or otherwise have an increased risk for SARS-CoV-2 exposure and transmission; and
4. Onset of MIS-C occurred before any COVID-19 vaccination.

COVID-19 vaccination may also be considered for people with a history of MIS-C who do not meet all the above criteria or for people with a history of MIS-A. Experts view clinical recovery, including return to normal cardiac function, as an important factor when considering COVID-19 vaccination. Additional factors when considering individual benefits and risks may include:

1. An increased personal risk of severe COVID-19 (e.g., age, underlying conditions)
2. Timing of immunomodulatory therapies (ACIP's general best practice guidelines for immunization can be consulted for more information)

People diagnosed with MIS-C or MIS-A after COVID-19 vaccination

In the rare instance of a person developing MIS-C, MIS-A, or a similar clinical illness after receipt of a COVID-19 vaccine, referral to a specialist in infectious diseases, rheumatology, or cardiology should be considered. Because MIS-C and MIS-A are conditions known to occur with SARS-CoV-2 infection, these individuals should be assessed for laboratory evidence of current or prior SARS-CoV-2 infection. Healthcare and public health professionals should also consider requesting a consultation from the Clinical Immunization Safety Assessment COVIDvax project. In addition, all illnesses consistent with MIS-C or MIS-A occurring in persons who received any COVID-19 vaccine should be reported to VAERS .

People who received passive antibody products

Currently, there are limited data available on the safety and effectiveness of COVID-19 vaccines in people who received passive antibody products (anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma)

as part of COVID-19 treatment or post-exposure prophylaxis. Based on the estimated half-life of such products and the anticipated period of protection against infection (when receiving anti-SARS-CoV-2 monoclonal antibodies for post-exposure prophylaxis) or reinfection (when receiving passive antibody therapy for treatment), COVID-19 vaccination should be temporarily deferred as a precautionary measure during the time period specified below after receiving passive antibody products to avoid potential interference of the product with vaccine-induced immune responses:

- Passive antibody product used for post-exposure prophylaxis: defer COVID-19 vaccination for 30 days
- Passive antibody product used for COVID-19 treatment: defer COVID-19 vaccination for 90 days

However, if passive antibody products and a COVID-19 vaccine dose are administered within these recommended deferral periods (30 or 90 days), the vaccine dose does not need to be repeated.

For people receiving antibody products not specific to COVID-19 treatment (e.g., intravenous immunoglobulin, RhoGAM), administration of COVID-19 vaccines either simultaneously with or at any interval before or after receipt of an antibody-containing product is unlikely to substantially impair development of a protective antibody response to SARS-CoV-2. Thus, there is no recommended minimum interval between antibody therapies not specific to COVID-19 treatment and COVID-19 vaccination.

Vaccines other than COVID-19 vaccines, including inactivated and live vaccines, may be administered without regard to timing of anti-SARS-CoV-2 monoclonal antibodies. Vaccines for diseases other than COVID-19 can be administered without regard to timing following receipt of convalescent plasma except for measles- or varicella-containing vaccines, which should be administered at least 7 months after receipt of convalescent plasma.

Vaccinated people who subsequently develop COVID-19

COVID-19 treatment-specific clinical guidelines (such as those published by the National Institutes of Health and the Infectious Diseases Society of America) should be consulted when making treatment decisions (including use of anti-SARS-CoV-2 monoclonal antibodies, convalescent plasma, antiviral treatment, or corticosteroid administration) for people who have previously received one or more doses of COVID-19 vaccine and subsequently develop COVID-19.

For purposes of surveillance, infections in fully vaccinated people (i.e., "breakthrough" infections) are defined as detection of SARS-CoV-2 RNA or antigen in a respiratory specimen collected ≥14 days after completion of all recommended doses of a currently FDA-approved or FDA-authorized COVID-19 vaccine. Infections in fully vaccinated people that result in hospitalization or death should be reported to VAERS .

Vaccinating people with a known COVID-19 exposure or

during COVID-19 outbreaks

COVID-19 vaccines are not currently recommended for outbreak management or for post-exposure prophylaxis to prevent SARS-CoV-2 infection in a person with a known exposure. Because the median incubation period of COVID-19 is 4–5 days, it is unlikely that a dose of COVID-19 vaccine would provide an adequate immune response within the incubation period for effective post-exposure prophylaxis.

Unvaccinated people in the community or in outpatient settings who have had a known COVID-19 exposure should not seek vaccination until their quarantine period has ended to avoid potentially exposing healthcare personnel and others during the vaccination visit. This also avoids causing diagnostic confusion between possible adverse effects of vaccination and symptoms of a new COVID-19 diagnosis. This recommendation also applies to people with a known COVID-19 exposure before receipt of the primary series, an additional primary dose, or booster dose.

Residents or patients with a known COVID-19 exposure or undergoing screening in congregate healthcare settings (e.g., long-term care facilities and other long-term care settings) or congregate non-healthcare settings (e.g., correctional and detention facilities, homeless shelters) may be vaccinated. In these settings, exposure to and transmission of SARS-CoV-2 can occur repeatedly for long periods of time, and healthcare personnel and other staff are already in close contact with residents. People residing in congregate settings (healthcare and non-healthcare) who have had an exposure and are awaiting SARS-CoV-2 testing results may be vaccinated if they do not have symptoms consistent with COVID-19. Vaccination providers should employ appropriate infection prevention and control procedures.

Vaccinating people receiving medical care unrelated to COVID-19 or undergoing SARS-CoV-2 screening

Provision of medical care in an inpatient or outpatient setting (e.g., outpatient clinic, urgent care center, emergency department) can serve as an opportunity to offer COVID-19 vaccination to people who are unvaccinated or who are eligible to receive a second dose of a 2-dose primary series, an additional primary dose, or a booster dose. Clinicians should discuss the importance of completing the recommended vaccination schedule with their patients who are unvaccinated, partially vaccinated, or whose vaccination status is unknown at the time of a clinical encounter. Similarly, unvaccinated people who are being screened for SARS-CoV-2 infection (e.g., work or school requirement, prior to travel) may be candidates for same-day vaccination. Considerations for administering COVID-19 vaccine include:

- Absence of symptoms consistent with COVID-19 or known current SARS-CoV-2 infection
- Absence of known close contact with someone with confirmed COVID-19
- Testing for SARS-CoV-2 not being done for diagnostic purposes

- Absence of a moderate or severe acute illness with or without a fever, to avoid diagnostic confusion between manifestations of the underlying illness and possible adverse effects of vaccination

Additional recommendations from ACIP's general best practices for immunization may be considered.

Considerations for COVID-19 vaccination in moderately and severely immunocompromised people

Immunocompromised people aged ≥5 years should receive a primary COVID-19 vaccine series as soon as possible. People with immunocompromising conditions or people who take immunosuppressive medications or therapies are at increased risk for severe COVID-19. The currently FDA-approved or FDA-authorized COVID-19 vaccines are not live vaccines and therefore can be safely administered to immunocompromised people.

Moderately and severely immunocompromised people may not mount a protective immune response after initial vaccination and, furthermore, their protection by primary vaccination may wane over time making them susceptible to severe COVID-19. ACIP and CDC have made age-specific recommendations for an additional primary dose and a booster dose for this population.

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
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell therapy or hematopoietic cell transplant (HCT) (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm^3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 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.

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. Age or place of residence alone (e.g., residence in a long-term care setting), independent of

a patient's medical condition, should not be used to determine the level of immune competence, as the balance of benefits and risks of an additional primary dose for people who are not moderately or severely immunocompromised is currently unknown.

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, can be consulted for additional information about the degree of immune suppression associated with different medical conditions and treatments. CDC's Interim Clinical Considerations, however, should be used to guide timing for COVID-19 vaccination (primary series, additional primary dose, and booster dose) in people with moderate and severe immunocompromise.

Recommendations for an additional primary dose of an mRNA COVID-19 vaccine in moderately and severely immunocompromised people after an initial 2-dose mRNA COVID-19 vaccine series

Moderately and severely immunocompromised persons aged ≥12 years (Pfizer-BioNTech recipients) or ≥18 years (Moderna recipients) should receive an additional primary dose of the same mRNA COVID-19 vaccine administered for the primary series ≥28 days after completion of the initial 2-dose series.[3]

Janssen COVID-19 Vaccine is not authorized for use as an additional primary dose, and people who received a single-dose Janssen primary vaccine should not receive an additional primary dose. Currently, CDC does not recommend an additional primary dose for children aged 5–11 years with moderate or severe immune compromise.

The additional primary mRNA COVID-19 dose should be the same vaccine product as the initial 2-dose mRNA COVID-19 primary series (Pfizer-BioNTech or Moderna). For people aged ≥18 years, if the mRNA COVID-19 vaccine product given for the first two doses is not available, the other mRNA COVID-19 vaccine product may be administered. If a mixed mRNA vaccine primary series was administered (one dose of Pfizer-BioNTech and one dose of Moderna), a person may still receive an additional primary dose of an mRNA COVID-19 vaccine at least 28 days after the second dose.

Recommendations for a COVID-19 booster dose in people aged ≥18 years who are moderately and severely immunocompromised

Moderately and severely immunocompromised people should follow the booster recommendations for the general population, based on their age and high-risk underlying condition. The following moderately and severely immunocompromised recipients of an mRNA COVID-19 vaccine primary series and an additional primary mRNA vaccine dose **should** receive a single COVID-19 booster dose (Pfizer-BioNTech, Moderna, or Janssen) at least 6 months after completing their additional primary dose:

- People aged ≥50 years

- Residents aged ≥18 years in long-term care settings

Moderately and severely immunocompromised recipients of an mRNA COVID-19 vaccine primary series and an additional primary mRNA vaccine aged 18-49 who do not reside in a long-term care setting **may** receive a single COVID-19 booster dose (Pfizer-BioNTech, Moderna, or Janssen) at least 6 months after completing their additional primary dose. Therefore, recipients of an mRNA primary series who are moderately and severely immunocompromised can receive an additional primary dose and booster dose for a total of four COVID-19 vaccine doses.

If a moderately or severely immunocompromised person aged ≥18 years has received two primary mRNA vaccine doses but has not yet received an additional mRNA primary dose, they should first receive the additional dose (at least 28 days after the second dose), followed by a single COVID-19 vaccine booster dose (at least 6 months after the additional dose). If Moderna is used, a dose of 100 µg (0.5 ml) should be used for the additional primary dose and 50 µg (0.25 ml) should be used for the booster dose.

Moderately and severely immunocompromised people aged ≥18 years who received a single dose Janssen COVID-19 Vaccine primary series **should** receive a single COVID-19 booster dose (Pfizer-BioNTech, Moderna [50 µg in 0.25ml], or Janssen) at least 2 months (8 weeks) after receiving their initial Janssen primary dose. A person who received one primary dose of Janssen COVID-19 Vaccine should not receive more than two COVID-19 vaccine doses.

Considerations for COVID-19 revaccination

HCT and CAR-T-cell recipients who received doses of COVID-19 vaccine prior to receiving an HCT or CAR-T-cell therapy should be revaccinated with a primary vaccine series at least 3 months (12 weeks) after transplant or CAR-T-cell therapy.

An additional primary dose of an mRNA COVID-19 vaccine (if revaccinated with a 2-dose mRNA COVID-19 vaccine primary series) is recommended as part of revaccination for persons who continue to have moderate or severe immune compromise. The additional primary dose of an mRNA COVID-19 vaccine should be administered at least 28 days after the second dose. A patient's clinical team is best positioned to determine the degree of immune compromise and appropriate timing of vaccination.

Considerations for timing of COVID-19 vaccination in relation to immunosuppressive therapies

Whenever possible, mRNA COVID-19 vaccine doses (primary series doses, additional primary dose, and booster dose) or Janssen COVID-19 Vaccine doses (primary dose or booster dose) should be completed at least two weeks before initiation or resumption of immunosuppressive therapies. Timing of COVID-19 vaccination should take into consideration current or planned immunosuppressive therapies and optimization of both the patient's medical condition and response to vaccine.

A patient's clinical team is best positioned to determine the degree of immune compromise and

appropriate timing for administration of the primary series, additional primary dose, booster dose, and COVID-19 revaccination (HCT and CAR-T-cell recipients).

The utility of serologic testing or cellular immune testing to assess immune response to vaccination and guide clinical care (e.g., as part of need assessment for an additional primary dose) has not been established. Serologic testing or cellular immune testing outside of the context of research studies is **not recommended at this time**.

Reinforcement of the need for prevention measures among immunocompromised people

For public health purposes, immunocompromised people who have completed a 2-dose mRNA primary vaccine series (Pfizer-BioNTech or Moderna) or a single dose of Janssen primary vaccine are considered fully vaccinated ≥2 weeks after completion of the series. The definition of fully vaccinated applies to people who are recommended to receive an additional primary dose and those recommended to receive a booster dose.

People who are immunocompromised **(including people who receive an additional primary dose or a booster dose)** should be counseled about the potential for a reduced immune response to COVID-19 vaccines and **the need to continue to follow current prevention measures** (including wearing a mask, staying 6 feet apart from others they don't live with, and avoiding crowds and poorly ventilated indoor spaces) to protect themselves against COVID-19 until advised otherwise by their healthcare professional. Close contacts of immunocompromised people should also be strongly encouraged to be vaccinated against COVID-19 to protect these people.

Considerations for use of a COVID-19 vaccine booster dose

Recommendations for use of a single COVID-19 booster dose after completion of a primary series can be found in the Overview of COVID-19 vaccine recommendations. CDC recommends that people who received an mRNA COVID-19 primary series and are aged ≥65 years, residents aged ≥18 years in long-term care settings, or aged 50–64 years with certain underlying medical conditions **should** receive a single COVID-19 vaccine booster ≥6 months after completion of their primary mRNA vaccine series. People aged ≥18 years who received a Janssen primary series should also receive a single COVID-19 vaccine booster ≥2 months after their Janssen primary dose. Currently, a booster dose is not recommended in people aged <18 years.

Individual benefit-risk assessment considerations for receiving a booster dose

CDC recommends that people aged 18–49 years with certain medical conditions, including pregnancy, and

people aged 18–64 years and at increased risk for SARS-CoV-2 exposure and transmission because of occupational or institutional setting **may** receive an mRNA COVID-19 booster dose based on their individual benefits and risks.

The benefits of a COVID-19 booster dose may include a reduced risk of SARS-CoV-2 infection and a reduced risk for severe COVID-19. Receiving a booster dose may prevent morbidity (including post-COVID symptoms) and may reduce transmission of the virus to other people. People in this risk category should consider the following risk factors for SARS-CoV-2 infection and the potential impact of SARS-CoV-2 infection:

- *Risk of exposure to SARS-CoV-2:* Factors that would be expected to affect the risk of exposure to SARS-CoV-2 include work or residence in certain settings; level of community transmission; rates of COVID-19 vaccination in their community; the likelihood of frequent interactions with possibly unvaccinated people from outside an individual's household; and adherence to current prevention measures.
- *Risk for developing SARS-CoV-2 infection:* A person's risk for developing SARS-CoV-2 infection may vary based on time from completing a primary COVID-19 vaccine series and time from prior SARS-CoV-2 infection due to waning immunity. Serologic testing or cellular immune testing is not recommended as part of the individual risk benefit assessment.
- *Risk for severe infection related to underlying conditions:* A person's risk of developing severe COVID-19 may vary by the type, number, and level of control of specific medical conditions as well as other yet to be defined variables. Pregnant people may receive a COVID-19 vaccine booster. Separately, also see section on Considerations for COVID-19 vaccination in moderately and severely immunocompromised people.
- *Potential impact of SARS-CoV-2 infection:* SARS-CoV-2 infections that are not severe may still lead to morbidity (e.g., post-COVID-19 symptoms). A person's individual circumstances should also be considered; these may include living with/caring for a person who is medically frail or immunocompromised or a child who is not eligible for COVID-19 vaccine or the inability to work or meet other personal obligations when infected, even if not severely ill with COVID-19.

Individual benefit-risk considerations for selecting which booster dose to receive

For groups recommended to receive a booster, people have the option to receive any of the FDA-approved or FDA-authorized COVID-19 booster products (Pfizer-BioNTech, Moderna [50 µg in a volume of 0.25ml], or Janssen). People may consider the benefits and risks of each product and discuss with their healthcare provider which product is most appropriate for them.

Clinical trial data show that homologous COVID-19 booster doses (utilizing the same vaccine product for the primary series and booster dose) increase the immune response against SARS-CoV-2 and have an acceptable safety profile for all FDA-approved or FDA-authorized COVID-19 vaccine boosters (Pfizer-

BioNTech , Moderna [50 µg in a volume of 0.25ml], or Janssen).

One study of heterologous (mix-and-match) booster dosing showed that all three of the FDA-approved or FDA-authorized vaccine boosters doses led to a strong serologic response in groups primed by all three vaccines. For a given COVID-19 primary vaccine series, heterologous boosters elicited similar or higher serologic responses as compared to their respective homologous booster responses.

People may also discuss with their healthcare provider the risks of different FDA-approved or FDA-authorized vaccines. The frequency and type of transient local and systemic symptoms after a booster dose are generally similar to those experienced after a primary series. Anaphylaxis is a rare risk, but the rate of anaphylaxis after a booster dose is not yet known.

Potential risks of an mRNA COVID-19 booster dose include the rare risks of myocarditis and pericarditis. Based on data after mRNA COVID-19 primary series, the group at the highest risk for myocarditis and pericarditis are males aged 12–29 years. Considerations for mRNA COVID-19 vaccines can be consulted for additional information.

Potential risks of a Janssen COVID-19 booster include the rare risks of Guillain-Barré Syndrome (GBS) and thrombosis with thrombocytopenia syndrome (TTS). Based on data after receipt of a Janssen COVID-19 primary dose, the group at the highest risk for GBS are men aged 50–64 years and the group highest at risk for TTS are women aged 18–49 years. Women aged 18–49 years should be made aware of the increased risk for TTS and the availability of mRNA COVID-19 vaccines for use as a booster dose. People who developed TTS after their initial Janssen Vaccine should not receive a Janssen booster dose. Considerations for Janssen COVID-19 Vaccine can be consulted for additional information.

Consult Considerations for COVID-19 vaccination in moderately and severely immunocompromised people for guidance on the use of booster doses in people who are moderately and severely immunocompromised.

Considerations involving pregnancy, lactation, and fertility

COVID-19 vaccination is recommended for people who are pregnant, lactating, trying to get pregnant now, or who might become pregnant in the near future. Any of the currently FDA-approved or FDA-authorized COVID-19 vaccines can be administered to people in these groups; ACIP and CDC do not state a product preference. This is applicable for a primary series, additional primary doses, and booster doses. However, all women aged <50 years should be aware of the rare risk of TTS after receipt of the Janssen COVID-19 Vaccine and the availability of other currently FDA-approved or FDA-authorized COVID-19 vaccines (i.e., mRNA vaccines for use as a primary series or booster dose) for which this risk has not been seen. See also People with a history of thrombosis or risk factors for thrombosis. There is no evidence that any of the COVID-19 vaccines affect current or future fertility. For purposes of decisions around

administering both primary series vaccination and a booster dose, pregnant and recently pregnant people (for at least 42 days following end of pregnancy) should be considered in the same group as people with underlying medical conditions.

Pregnancy

Pregnant and recently pregnant people (for at least 42 days following the end of pregnancy) with COVID-19 are at increased risk for severe illness when compared with non-pregnant people. Severe illness includes illness that requires hospitalization, intensive care unit admission, mechanical ventilation, or extracorporeal membrane oxygenation or illness that results in death, although the absolute risk for these outcomes is low. Additionally, pregnant people with COVID-19 are at increased risk for preterm birth and might be at increased risk for other adverse pregnancy complications and outcomes, such as preeclampsia, coagulopathy, and stillbirth.

A growing body of evidence on the safety and effectiveness of COVID-19 vaccination—in both animal and human studies—indicates that the benefits of vaccination outweigh any known or potential risks of COVID-19 vaccination during pregnancy.

- *COVID-19 vaccines do not cause infection in the pregnant person or the fetus:* The currently FDA-approved or FDA-authorized COVID-19 vaccines (i.e., mRNA vaccines and a non-replicating viral vector vaccine) are not live vaccines and cannot cause infection in either the pregnant person or the fetus.
- *Reassuring early safety data on mRNA COVID-19 vaccines during pregnancy:* CDC released the first U.S. data on the safety of mRNA COVID-19 vaccines administered during pregnancy. The report analyzed data from three vaccine safety-related databases: VAERS , the v-safe active surveillance system, and the v-safe pregnancy registry, which collects additional detailed data on pregnant people and their infants. Early data from these systems did not identify any safety concerns for pregnant people who were vaccinated late in their pregnancy or their infants. Additional studies examined data from people who received an mRNA vaccine before 20 weeks' gestation and found no increased risk for miscarriage .
- *Early data suggest mRNA COVID-19 vaccines during pregnancy are effective:* A study from a large population-based cohort of pregnant people in Israel compared those who received mRNA COVID-19 vaccination with those who did not and found vaccination was associated with a significantly lower risk of SARS-CoV-2 infection.
- *Vaccination of pregnant people generates an immune response:* A recent report has shown that mRNA COVID-19 vaccine-induced humoral response was comparable in pregnant women and non-pregnant controls. In the same study, antibodies developed from mRNA COVID-19 vaccination were present in umbilical cord blood, indicating the potential for protection against COVID-19 for neonates and infants.

- *Clinical trials to evaluate the safety and efficacy of COVID-19 vaccines in pregnant people are under way*: Vaccine manufacturers are also following outcomes in people in the clinical trials who became pregnant.
- *No safety signals in animal studies:* No female reproduction or fetal, embryonal, or postnatal development safety concerns were demonstrated in animals that received Pfizer-BioNTech, Moderna, or Janssen COVID-19 Vaccines before or during gestation.
- *No adverse outcomes in previous trials of the adenovirus vector platform that included pregnant people:* The adenovirus vector platform used in the Janssen COVID-19 Vaccine has been used for other Janssen vaccine development programs in which pregnant people were vaccinated during any trimester, including a large-scale Ebola vaccine trial. No adverse pregnancy-related outcomes—including infant outcomes—were determined to be related to the vaccine in these trials.

COVID-19 vaccination is recommended for all people who are pregnant. A conversation between the patient and their clinical team may assist with decisions about the use of a COVID-19 vaccine; however, approval by a healthcare professional is not required before vaccination. COVID-19 vaccines and other vaccines may be administered without regard to timing as detailed in Coadministration with other vaccines. If a person becomes pregnant following the first dose of a COVID-19 vaccine that requires two doses for the primary series (i.e., Pfizer-BioNTech or Moderna), the second dose should be administered as indicated for the person to have maximum protection. Data on uptake of COVID-19 vaccination among pregnant people can be found on CDC's COVID Data Tracker. Pregnant people are encouraged to enroll in v-safe after COVID-19 vaccination.

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.

Lactation

COVID-19 vaccination is recommended for all lactating people. There are limited data on the safety of COVID-19 vaccines in lactating people or the effects of COVID-19 vaccines on the breastfed infant, milk production, and secretion. However, the currently FDA-approved or FDA-authorized COVID-19 vaccines (i.e., mRNA vaccines and a non-replicating viral vector vaccine) cannot cause infection in either the lactating person or the infant. Recent reports have shown that the antibodies developed from mRNA COVID-19 vaccination were present in breastmilk samples. More data are needed to determine if these antibodies convey protection against SARS-CoV-2 infection for neonates and infants.

Fertility

COVID-19 vaccination is recommended for all people trying to get pregnant now or who might become pregnant in the future. There is no recommendation for routine pregnancy testing before receipt of a

COVID-19 vaccine. Those who are trying to become pregnant do not need to avoid pregnancy after COVID-19 vaccination. There is currently no evidence that any vaccines, including COVID-19 vaccines, cause fertility problems. Many women have become pregnant after receiving COVID-19 vaccine. However, results from ongoing long-term fertility studies are not yet available.

Vaccination of children and adolescents

The COVID-19 pandemic has had significant impacts on the health and well-being of children. While children and adolescents are less likely to develop severe COVID-19 compared to older adults, severe illness (i.e., hospitalization, intensive care unit admission, death), and complications of SARS-CoV-2 infection (e.g., MIS-C, post-COVID conditions) do occur in this population. Among children and adolescents with severe COVID-19, no identifiable risk factor, such as an underlying medical condition, has been reported for approximately one third of cases. In addition, SARS-CoV-2 infection or exposure results in other negative impacts, such as school absences and social isolation.

COVID-19 vaccine recommendations for children and adolescents

Children and adolescents aged 5–17 years are recommended to receive the age-appropriate formulation of a COVID-19 primary vaccine series. At this time, the 2-dose Pfizer-BioNTech primary series is the only FDA-approved or FDA-authorized vaccine for children and adolescents aged 5–17. Although many children and adolescents may have experienced prior SARS-CoV-2 infection , COVID-19 primary vaccination is recommended for everyone aged 5 years and older, regardless of a history of underlying medical conditions, symptomatic or asymptomatic SARS-CoV-2 infection, or seropositivity.

Data from clinical trials in children indicate that Pfizer-BioNTech vaccines can be given safely to children with evidence of a prior SARS-CoV-2 infection. Data, predominately from adults, suggests that protection from SARS-CoV-2 reinfection is high after initial infection but decreases with time due to waning immunity. Growing epidemiologic evidence from adults and adolescents indicates that vaccination following infection further increases protection from subsequent infection, including in the setting of increased circulation of more infectious variants. Serologic testing to assess for prior infection is not recommended for the purpose of vaccine decision-making. More information on vaccination after SARS-CoV-2 infection can be found here.

Moderately and severely immunocompromised persons aged ≥12 years (Pfizer-BioNTech recipients) or ≥18 years (Moderna recipients) should receive an additional primary dose of the mRNA COVID-19 vaccine administered for the primary series. Currently, an additional primary dose in children aged 5–11 years with moderate and severe immune compromise is not recommended.

Booster doses are not recommended for people <18 years of age.

Children and adolescents may be vaccinated with appropriate consent and assent. Sites administering COVID-19 vaccines should follow current state/jurisdictional policies and practices for other routine vaccinations in this age group.

Dosing and formulation

Children should receive the age-appropriate vaccine formulation regardless of their size or weight. Children aged 5–11 years should receive the 10 µg Pfizer-BioNTech COVID-19 Vaccine (orange cap) formulation and adolescents aged ≥12 years should receive the 30 µg Pfizer-BioNTech COVID-19 Vaccine (purple cap) formulation or COMIRNATY. In contrast to many medications, vaccine dosages (for COVID-19 vaccines and for other routinely recommended vaccines) are based on age and not size or weight. Different dosages are evaluated during vaccine development to determine the lowest effective dose for the target age group. Clinical trials evaluate various dosing regimens to determine the best dosage and schedule that produces an adequate immune response which is both safe and effective.

Children should receive the vaccine dosage and formulation based on their age on the day of vaccination with each dose. If a child turns 12 years old between their first and second dose, they should receive the age-appropriate 30 µg Pfizer-BioNTech COVID-19 Vaccine (purple cap) formulation or COMIRNATY for their second dose to complete their series. However, the FDA authorization allows children who will turn from 11 years to 12 years of age between their first and second dose in the primary regimen to receive, for either dose, either: (1) the Pfizer-BioNTech COVID-19 Vaccine formulation for children aged 5–11 years (each 0.2 ml dose containing 10 µg in an orange cap vial); or (2) COMIRNATY or the Pfizer-BioNTech COVID-19 Vaccine formulation authorized for use in individuals 12 years of age and older (each 0.3 mL dose containing 30 mcg in a purple cap vial). If such dosing occurred, the child is considered fully vaccinated. This is not considered an error and VAERS reporting is not indicated.

Reactogenicity and adverse events

Available safety and immunogenicity data for Pfizer-BioNTech COVID-19 vaccines in children and adolescents are similar to those seen in young adults. Local and systemic reactions following vaccination are less frequent in children aged 5–11 years compared with young adults aged 16–25 years.

Syncope (fainting) may occur in association with any injectable vaccine, especially in adolescents. Procedures should be in place to prevent falling injuries and manage syncopal reactions. People should be seated or lying down during vaccination. Vaccination providers, particularly when vaccinating adolescents, should consider observing vaccine recipients for 15 minutes after vaccination to decrease the risk for injury should they faint. If syncope develops, patients should be observed until symptoms resolve.

Myocarditis is a rare, serious adverse event that has been reported after receipt of the second dose of mRNA COVID-19 vaccines, with the highest risk currently observed in males aged 12–29 years. FDA has authorized and ACIP and CDC have recommended Pfizer-BioNTech vaccines in children aged 5–11 years

and adolescents aged 12–17 years based on the determination that the benefits of COVID-19 vaccination outweigh risks in these populations. More information on myocarditis and COVID-19 vaccination can be found here.

Administration errors

If a child aged 5–11 years inadvertently receives a 30 µg dose of Pfizer-BioNTech COVID-19 Vaccine/COMIRNATY for their first dose, a single, age-appropriate dose should be administered as a second dose 21 days later. If a child aged 5–11 years inadvertently receives a 30 µg dose for their second dose, the primary series is considered complete and no subsequent doses are recommended. If a person aged 12–17 years inadvertently receives a 10µg dose of Pfizer-BioNTech COVID-19 Vaccine (5–11 years formulation), the dose does not need to be repeated. However, based on clinical judgement (e.g., the adolescent received two doses of the incorrect formulation), a repeat dose of Pfizer-BioNTech COVID-19 Vaccine ≥12 years formulation (30 µg, purple cap) may be administered at an interval of 21 days after the dose given in error. If the dose given in error is the first dose, administer the second Pfizer-BioNTech COVID-19 Vaccine ≥12 years formulation (30 µg, purple cap) 21 days later to complete the primary series. See above section on "Dosing and formulation" for further information on children who will turn from 11 years to 12 years between their first and second dose.

Information on preventing, reporting, and managing COVID-19 vaccine administration errors is found in Appendix A. Administration errors should be reported to VAERS .

Children younger than age 5 years are not eligible to receive the Pfizer-BioNTech COVID-19 Vaccine at this time unless part of a clinical trial. Children and adolescents younger than age 18 years are not eligible to receive the Moderna or Janssen COVID-19 vaccines at this time.

Patient counseling

Pre-vaccination counseling

The vaccine-specific Fact Sheet for Recipients and Caregivers (Pfizer-BioNTech, Moderna , Janssen) should be provided to all vaccine recipients, parents or guardians, and caregivers (when relevant) before vaccination with any currently FDA-approved or FDA-authorized COVID-19 vaccine.

Potential for local and systemic reactions

Before vaccination, providers should counsel COVID-19 vaccine recipients, parents, or guardians about expected local (e.g., pain, swelling, erythema at the injection site) and systemic (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) post-vaccination reactions. Localized axillary lymphadenopathy[5] on the same side as the vaccinated arm has been observed following vaccination with mRNA COVID-19

vaccines. Routine prophylactic administration of antipyretic or analgesic medications (e.g., acetaminophen, non-steroidal anti-inflammatory drugs) for the purpose of preventing post-vaccination symptoms is **not recommended.**

Anaphylactic reactions have been rarely reported following receipt of COVID-19 vaccines. Administration of antihistamines to COVID-19 vaccine recipients before 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.

Use of aspirin or anticoagulants

It is not recommended that people take aspirin or an anticoagulant before vaccination with any currently FDA-approved or FDA-authorized COVID-19 vaccine, including Janssen COVID-19 Vaccine, unless they take these medications as part of their routine medications.

Management of post-COVID-19-vaccination symptoms

For all currently FDA-approved or FDA-authorized COVID-19 vaccines, antipyretic or analgesic medications can be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate. However, in general, aspirin is **not recommended** for use in children and adolescents ≤18 years of age as an antipyretic or analgesic due to the risk of Reye's syndrome.

Additional guidance is available for assessing and responding to post-vaccination signs and symptoms in workplaces, including healthcare settings, and among long-term care facility residents.

Special populations

People with autoimmune conditions

People with autoimmune conditions were enrolled in COVID-19 vaccine clinical trials. Safety and efficacy of vaccines in this population were similar to the general population. People with autoimmune conditions may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine. If people with these conditions are immunocompromised because of medications such as high-dose corticosteroids or biologic agents, they should consult Considerations for COVID-19 vaccination in moderately and severely immunocompromised people.

People with a history of Bell's palsy

Cases of Bell's palsy (acute peripheral facial nerve palsy) were reported following vaccination of participants in the COVID-19 vaccine clinical trials. Available data were insufficient for FDA to conclude that these cases were causally related to vaccination. People with a history of Bell's palsy may receive any currently FDA-

approved or FDA-authorized COVID-19 vaccine. Any occurrence of Bell's palsy following COVID-19 vaccination should be reported to VAERS .

People with a history of dermal filler use

Infrequently, people who have received dermal fillers might experience swelling at or near the site of filler injection (usually face or lips) following administration of a dose of an mRNA COVID-19 vaccine (no similar occurrences were observed in the Janssen COVID-19 Vaccine clinical trials). The swelling appears to be temporary and resolves with medical treatment, including corticosteroid therapy. Any currently FDA-approved or FDA-authorized COVID-19 vaccine can be administered to people who have received injectable dermal fillers. People should be advised to contact their healthcare professional for evaluation if they experience swelling at or near a dermal filler site following vaccination.

People receiving antiviral therapy

Administration of an antiviral drug at any interval before or after vaccination with any of the currently FDA-approved or FDA-authorized COVID-19 vaccines, including the adenovirus vector Janssen COVID-19 Vaccine, is unlikely to impair development of a protective antibody response.

Considerations for mRNA COVID-19 vaccines: Pfizer-BioNTech and Moderna

Post-vaccination symptoms

In clinical trials of Pfizer-BioNTech and Moderna COVID-19 Vaccines, pain at the injection site was the most frequent and severe local reaction. Fatigue, headache, and myalgia were the most common systemic symptoms; most systemic symptoms were mild to moderate in severity; occurred within the first three days of vaccination; and resolved within 1–2 days of onset. Overall, symptoms were more frequent and severe following the second dose of vaccine and among adolescents and young adults compared with older people (i.e., aged >55 or ≥65 years [for Pfizer-BioNTech or Moderna vaccines, respectively]). See Vaccination of children and adolescents for reactogenicity information in these populations.

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

Myocarditis and pericarditis

Myocarditis and/or pericarditis have occurred rarely in some people following receipt of mRNA COVID-19 vaccines. Among people ≥12 years, cases have occurred predominantly in males aged 12-29 years within the first week after receiving the second dose of vaccine. Most patients have been hospitalized for short

periods, with most achieving resolution of acute symptoms. The risk of myocarditis or pericarditis associated with SARS-CoV-2 infection is greater than the risk of myocarditis or pericarditis occurring after receipt of an mRNA COVID-19 vaccine in adolescents and adults. No cases of myocarditis were reported among the 3,082 participants aged 5–11 years in Pfizer-BioNTech's vaccine trial with at least 7 days of follow up after receipt of dose 2, although the study was not powered to assess the risk for myocarditis. The observed risk of myocarditis after mRNA COVID-19 vaccination in adolescents may not be generalizable to younger children since the baseline risk of myocarditis prior to the pandemic is higher in children aged 12-17 years compared to children aged 5-11 years. After reviewing available data on the risks and benefits, ACIP determined that the benefits (e.g., prevention of COVID-19 cases) outweigh the risk of myocarditis or pericarditis after receipt of mRNA COVID-19 vaccines for children , adolescents, and young adults.

People receiving mRNA COVID-19 vaccines, especially males aged 12–29 years, should be made aware of both the possibility of myocarditis or pericarditis following receipt of mRNA COVID-19 vaccines and the possibility of myocarditis or pericarditis following SARS-CoV-2 infection, and should be counseled about the need to seek care if symptoms of myocarditis or pericarditis develop after vaccination. People should seek medical attention immediately if they develop any of the following symptoms after receiving an mRNA vaccine, particularly in the week after vaccination:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine but before administration of a subsequent dose of COVID-19 vaccine

There are no data on the safety of administering a subsequent dose of any COVID-19 vaccine to people who had myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine. It is unclear if people who developed myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine may be at increased risk of further adverse cardiac effects following a subsequent dose of the vaccine. **Until additional safety data are available, experts advise that people who develop myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine not receive a subsequent dose of any COVID-19 vaccine.**

Administration of a subsequent dose of COVID-19 vaccine before additional safety data are available can be considered in certain circumstances for people who develop myocarditis or pericarditis after receiving a dose of an mRNA COVID-19 vaccine. Considerations for vaccination may include:

- Personal risk of severe acute COVID-19 (e.g., age, underlying conditions)
- Level of COVID-19 community transmission and personal risk of infection

Timing of any immunomodulatory therapies; ACIP's general best practice guidelines for immunization can be consulted for more information

People who choose to receive a subsequent dose of a COVID-19 vaccine should wait at least until their episode of myocarditis or pericarditis has completely resolved. This includes resolution of symptoms attributed to myocarditis or pericarditis, as well as no evidence of ongoing heart inflammation or sequelae as determined by the person's clinical team, which may include a cardiologist, and special testing to assess cardiac recovery. For men aged ≥18 years who developed myocarditis or pericarditis after a dose of mRNA COVID-19 vaccine and who choose to receive a subsequent dose of COVID-19 vaccine before additional safety data are available, several experts advise that the Janssen COVID-19 Vaccine be considered instead of an mRNA COVID-19 vaccine. Decisions about proceeding with a subsequent dose should include a conversation between the patient, their parent, guardian, or caregiver (when relevant), and their clinical team.

Clinicians should consult current clinical guidance for information on the evaluation and management of myocarditis.

History of myocarditis or pericarditis prior to COVID-19 vaccination

There are limited data on the safety and efficacy of COVID-19 vaccines in people with a history of myocarditis or pericarditis. People who have a history of myocarditis or pericarditis unrelated to mRNA COVID-19 vaccination (e.g., due to SARS-CoV-2 or other viruses) may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved. This includes resolution of symptoms attributed to myocarditis or pericarditis, as well as no evidence of ongoing heart inflammation or sequelae as determined by the person's clinical team, which may include a cardiologist, and special testing to assess cardiac recovery. Considerations for COVID-19 vaccination in people with a history of MIS-C or MIS-A are discussed here.

CDC is continuing to investigate cases of myocarditis or pericarditis after mRNA COVID-19 vaccination; this guidance may be updated as new information is obtained. All cases of myocarditis or pericarditis following COVID-19 vaccination should be reported to VAERS □ .

Considerations for Janssen COVID-19 Vaccine

Post-vaccination symptoms

In clinical trials of Janssen COVID-19 Vaccine, pain at the injection site was the most frequently reported local reaction among vaccine recipients; erythema and swelling were reported less frequently. Fatigue and headache were the most commonly reported systemic reactions. Most systemic symptoms were mild to moderate in severity and resolved within 1–2 days. Overall, symptoms were more frequent in people aged

18–59 years compared to people aged ≥60 years.

Thrombosis with thrombocytopenia syndrome

Thrombosis with thrombocytopenia syndrome (TTS) is a rare syndrome that involves acute venous or arterial thrombosis and new onset thrombocytopenia in patients with no recent known exposure to heparin. In the United States, the majority of people with TTS that occurred after Janssen COVID-19 vaccination had clots located in cerebral venous sinuses; clots also occurred in other unusual locations, including in the portal vein and splenic vein, and included a combination of venous and arterial thromboses. Although the condition is rare , current evidence suggests a causal association of receipt of Janssen COVID-19 Vaccine with TTS. Most cases are in women, with most aged 18-49 years old.

Based on its review of a risk-benefit analysis, ACIP reaffirmed its interim recommendation for the use of the Janssen COVID-19 Vaccine in all persons aged ≥18 years, while acknowledging the increased risk for TTS in women aged 18-49 years. FDA updated the Janssen COVID-19 Vaccine EUA Fact Sheet for Health Care Providers Administering Vaccine (Vaccination Providers) and Fact Sheet for Recipients and Caregivers to include information about rare clotting events that might occur after vaccination, primarily among women aged 18–49 years. Women in this age group should be made aware of the increased risk for TTS and the availability of mRNA COVID-19 vaccines for use as a primary series or booster dose.

People should seek medical attention immediately if they develop any of the following symptoms after receiving the Janssen COVID-19 Vaccine:

- Shortness of breath
- Chest pain
- Leg swelling
- Persistent abdominal pain
- Severe or persistent headaches or blurred vision
- Easy bruising or tiny blood spots under the skin beyond the site of the injection.

There are no data on the safety of administering a booster dose of either the Janssen COVID-19 Vaccine or an mRNA COVID-19 vaccine to people who had TTS following the first dose. **Given the clinical severity of TTS, experts do not recommend administering a second dose of the Janssen Vaccine to people who had TTS after their first dose.** These people may receive a dose of an mRNA COVID-19 vaccine as a booster at least 2 months (8 weeks) following their dose of the Janssen Vaccine and after their clinical condition has stabilized. Prior to booster vaccination, a conversation between the patient and their clinical team, including a hematologist or other specialists, may assist with decisions about using an mRNA COVID-19 vaccine as a booster and the timing of the booster vaccination.

Clinicians should consult the Health Alert Network (HAN) notification and guidance from the American

Society of Hematology for information on the diagnosis and treatment of suspected cases of TTS.

People with a history of thrombosis or risk factors for thrombosis

Although the etiology of TTS associated with the Janssen COVID-19 Vaccine is unclear, it appears to be similar to another rare immune-mediated syndrome, heparin-induced thrombocytopenia (HIT). For unvaccinated people, until more information becomes available, experts advise that people with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as HIT, should be offered a currently FDA-approved or FDA-authorized mRNA COVID-19 vaccine if it has been ≤90 days since their TTS resolved. After 90 days, patients may be vaccinated with any currently FDA-approved or FDA-authorized COVID-19 vaccine, including Janssen COVID-19 Vaccine.

Venous thromboembolism (VTE), defined as deep vein thrombosis, pulmonary embolism, or both, are common. The biologic mechanisms for VTE (as well as arterial thrombi) differ from the underlying immune-mediated mechanism for HIT. Based on current knowledge, experts believe that people with risk factors for VTE (e.g., inherited or acquired thrombophilia including Factor V Leiden; prothrombin gene 20210A mutation; antiphospholipid syndrome; protein C, protein S or antithrombin deficiency), or a prior history of other types of thromboses (including cerebral venous sinus thrombosis [CVST]) not associated with thrombocytopenia are unlikely to be at increased risk for TTS. Likewise, although the risk of thrombosis is increased during pregnancy and the postpartum period, and with certain hormonal contraceptives (e.g., combined oral contraceptives, patch, and ring), experts believe that these factors do not make people more susceptible to TTS after receipt of the Janssen COVID-19 Vaccine. People with risk factors for VTE can receive any currently FDA-approved or FDA-authorized vaccine, including the Janssen COVID-19 Vaccine.

Guillain-Barré syndrome

People with a history of Guillain-Barré syndrome (GBS) can receive any currently FDA-approved or FDA-authorized COVID-19 vaccine. ACIP's general best practices for immunization do not include a history of GBS as a contraindication to vaccination; a history of GBS is a precaution for influenza vaccines and tetanus-toxoid containing vaccines in limited situations.[6]

Vaccine safety monitoring suggests a possible association between GBS and Janssen COVID-19 vaccination with proportionally more GBS cases observed after Janssen COVID-19 vaccination compared to mRNA COVID-19 vaccination. The highest risk has been observed in males aged 50-64 years with symptoms of GBS beginning within 42 days after Janssen COVID-19 vaccination.

Based on its review of a benefit-risk assessment , ACIP reaffirmed its interim recommendation for the use of the Janssen COVID-19 Vaccine in all persons aged ≥18 years while acknowledging the increased risk for GBS. People with a history of GBS and their clinical team should discuss the availability of mRNA COVID-19 vaccines to offer protection against COVID-19.

People should seek medical attention immediately if they develop any of the following symptoms after receiving Janssen COVID-19 Vaccine:

- Weakness or tingling sensations, especially in the legs or arms, that is worsening and spreading to other parts of the body
- Difficulty walking
- Difficulty with facial movements, including speaking, chewing, or swallowing
- Double vision or inability to move eyes
- Difficulty with bladder control or bowel function

There are no data on the safety of administering a booster dose of either Janssen Vaccine or an mRNA vaccine to people who had GBS following the first dose of Janssen Vaccine. People who had GBS after receiving Janssen Vaccine should be made aware of the option to receive an mRNA COVID-19 vaccine booster dose at least 2 months after the Janssen dose. However, Janssen Vaccine may be used as a booster, particularly if GBS occurred more than 42 days after vaccination or was related to a non-vaccine factor. Prior to booster vaccination, a conversation between the patient and their clinical team, including a neurologist or other specialists, may assist with decisions about use of a COVID-19 booster dose, including the timing of administration.

Any occurrence of GBS following COVID-19 vaccination should be reported to VAERS □ . CDC and FDA will continue to monitor and review cases of GBS among people who receive any currently FDA-approved or FDA-authorized COVID-19 vaccine in the United States and may update this guidance in the future.

Contraindications and precautions

Contraindications and precautions to COVID-19 vaccines are described below and summarized in Appendix B. For the purposes of this guidance, regarding timing of allergic reactions, an immediate allergic reaction to a vaccine or injectable therapy is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

For the purposes of this guidance, regarding severity of allergic reactions:

Severe allergic reactions include:

- Possible anaphylaxis, a progressive life-threatening reaction that typically includes urticaria but also with other symptoms such as wheezing, difficulty breathing, or low blood pressure (see Appendix D)
- Any angioedema affecting the airway (i.e., tongue, uvula, or larynx)

- Diffuse rash which also involves mucosal surfaces (e.g., Stevens-Johnson Syndrome)

Non-severe allergic reactions may include:

- Urticaria (hives) beyond the injection site
- Angioedema (visible swelling) involving lips, facial skin, or skin in other locations. NOTE: Any angioedema affecting the airway (i.e., tongue, uvula, or larynx) is considered a severe allergic reaction (see above).

Healthcare professionals or health departments in the United States can request a consultation from the Clinical Immunization Safety Assessment COVIDvax project about an individual patient residing in the United States for a complex COVID-19 vaccine safety question not readily addressed by CDC guidance.

Contraindications

CDC considers a history of the following to be a contraindication to vaccination with COVID-19 vaccines:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
- Known diagnosed allergy to a component of the COVID-19 vaccine

See Appendix C for a list of ingredients in COVID-19 vaccines. Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 Vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur. People with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna). However, people with a contraindication to mRNA COVID-19 vaccines may be able to receive Janssen COVID-19 Vaccine, and vice versa, provided certain measures are taken (see "Risk assessment" below). Known polysorbate allergy is no longer a contraindication to mRNA vaccination; however, known polysorbate allergy is a contraindication to Janssen COVID-19 Vaccine and thus, a precaution to mRNA COVID-19 vaccination.

Healthcare professionals should attempt to determine whether reactions reported following vaccination are consistent with immediate allergic reactions versus other types of reactions commonly observed following vaccination, such as a vasovagal reaction or post-vaccination side effects (Appendix D). In addition, it is important to assess the severity of any immediate allergic reaction, as it relates to the overall risk to life or health of the individual. This will help determine which patients have a contraindication to vaccination, including to the second dose of an mRNA COVID-19 vaccine.

Precautions

Most people deemed to have a precaution to a COVID-19 vaccine at the time of their vaccination

appointment can and should be administered vaccine. CDC considers a history of an immediate allergic reaction to any vaccine other than COVID-19 vaccine or to any injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"]) as a precaution but not a contraindication to vaccination. People with a history of an immediate allergic reaction to a non-COVID-19 vaccine or injectable therapy that contains multiple components, one or more of which is a component of a COVID-19 vaccine, but it is unknown which component elicited the allergic reaction, have a precaution to vaccination with that COVID-19 vaccine. These people may benefit from consultation with an allergist-immunologist who can perform a more detailed risk assessment for COVID-19 vaccine receipt and possibly allergy testing.

Available data support that people who had an immediate (onset <4 hours after vaccination), but non-severe, allergic reaction after a dose of one type of COVID-19 vaccine (i.e., mRNA COVID-19 vaccines or Janssen COVID-19 Vaccine) are considered to have a precaution for receipt of a subsequent dose of that same vaccine type. Referral to an allergist-immunologist may be considered. See "Risk assessment" below about the appropriate settings for subsequent vaccination of these people when using the same vaccine type. Administering the other vaccine type is another option; this can be done with a 30-minute observation period in a usual COVID-19 vaccination setting.

People with a contraindication to one type of the currently FDA-approved or FDA-authorized COVID-19 vaccines (e.g., mRNA) have a precaution to the other (e.g., Janssen viral vector). However, because of potential cross-reactive hypersensitivity between ingredients in mRNA and Janssen COVID-19 Vaccines, consultation with an allergist-immunologist should be considered to help determine if the patient can safely receive vaccination. Healthcare professionals and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project. Vaccination of these individuals should only be undertaken in an appropriate setting under the supervision of a healthcare professional experienced in the management of severe allergic reactions.

- People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy): Consideration may be given to vaccination with Janssen COVID-19 Vaccine. People who have received a first mRNA COVID-19 vaccine dose but for whom the second dose is contraindicated should wait at least 28 days after the mRNA vaccine dose to receive Janssen COVID-19 Vaccine.
- People with a contraindication to Janssen COVID-19 Vaccine (including due to a known polysorbate allergy): Consideration may be given to mRNA COVID-19 vaccination. Of note, polysorbate allergy is no longer a contraindication to mRNA COVID-19 vaccination, it is a precaution.

Risk assessment: The following considerations can be used to help the vaccination provider conduct a risk assessment for vaccination in individuals with a precaution to vaccination:

- Risk of exposure to SARS-CoV-2 (e.g., exposure because of occupational or institutional setting)
- Risk of severe disease or death due to COVID-19 (e.g., because of age, underlying medical

conditions)

- The unknown risk of anaphylaxis (including fatal anaphylaxis) following COVID-19 vaccination in a person with a history of an immediate allergic reaction to other vaccines or injectable therapies. Consultation with an allergist-immunologist may help to clarify the risk assessment for these individuals.
- Ability of the patient to be vaccinated in a setting where appropriate medical care is immediately available for anaphylaxis. Note that for people with a contraindication to one type of COVID-19 vaccine (e.g., mRNA vaccines), vaccination with another type (e.g., Janssen viral vector vaccine) should only be undertaken in an appropriate setting under the supervision of a healthcare professional experienced in the management of severe allergic reactions. Similarly, for people with an immediate, non-severe allergic reaction after a previous dose of that type of COVID-19 vaccine, vaccination with the subsequent dose of that vaccine type should only be undertaken in an appropriate setting under the supervision of a healthcare professional experienced in the management of severe allergic reactions.

Neither contraindications nor precautions to COVID-19 vaccination

Allergic reactions (including severe allergic reactions) not related to vaccines (COVID-19 or other vaccines) or injectable therapies, such as allergic reactions related to food, pet, venom, or environmental allergies, or allergies to oral medications (including the oral equivalents of injectable medications), are **not** a contraindication or precaution to COVID-19 vaccination. The vial stoppers of COVID-19 vaccines are not made with natural rubber latex, and there is no contraindication or precaution to vaccination for people with a latex allergy. In addition, because the COVID-19 vaccines do not contain eggs or gelatin, people with allergies to these substances do not have a contraindication or precaution to vaccination.

Delayed-onset local reactions have been reported after mRNA vaccination in some individuals beginning a few days through the second week after the first dose and are sometimes quite large. People with only a delayed-onset local reaction (e.g., erythema, induration, pruritus) around the injection site area after the first vaccine dose do not have a contraindication or precaution to a subsequent dose. For the mRNA primary vaccine series, these individuals should receive the second dose (or an additional primary dose, if indicated) using the same vaccine product as the first dose at the recommended interval, preferably in the opposite arm.

Observation periods following vaccination to monitor for allergic reactions

CDC recommends the following observation periods after COVID-19 vaccination:

- 30 minutes:
    - People with a contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to mRNA COVID-19 vaccines who receive Janssen viral vector vaccine

should be observed for 30 minutes following Janssen vaccination).
    - History of non-severe, immediate (onset less than 4 hours) allergic reaction after a previous dose of COVID-19 vaccine
    - History of an immediate allergic reaction of any severity to non-COVID-19 vaccines or injectable therapies
    - History of anaphylaxis due to any cause
- 15 minutes: All other people

Management of anaphylaxis after COVID-19 vaccination

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of COVID-19 vaccine. Further information on anaphylaxis management can be found in the interim considerations for the management of anaphylaxis following COVID-19 vaccination and laboratory evaluation of people who experience anaphylaxis after vaccination.

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 the FDA to report the following that occur after COVID-19 vaccination under BLA or EUA:

- Vaccine administration errors
- Serious adverse events
- Cases of Multisystem Inflammatory Syndrome
- 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.

In addition, CDC has developed a new voluntary, smartphone-based tool, **v-safe**. This tool uses text messaging and web surveys to provide near real-time health check-ins after patients receive COVID-19 vaccination. Reports to **v-safe** indicating a medically significant health impact, including pregnancy, are followed up by the CDC/**v-safe** call center to collect additional information to complete a VAERS report, if appropriate.

Laboratory testing

Vaccination and SARS-CoV-2 testing

Antibody testing is not currently recommended to assess the need for vaccination in an unvaccinated person or to assess for immunity to SARS-CoV-2 following COVID-19 vaccination. Antibody tests currently authorized under an EUA have variable sensitivity, specificity, as well as positive and negative predictive values, and are not authorized for the assessment of immune response in vaccinated people. Furthermore, the serologic correlates of protection have not been established, and antibody testing does not evaluate the cellular immune response, which may also play a role in vaccine-mediated protection.

If antibody testing was performed following vaccination, further doses of the same or different COVID-19 vaccines are not recommended based on antibody test results at this time. If antibody testing was done after the first dose of an mRNA vaccine, the vaccination series should be completed 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). To evaluate for evidence of prior infection in vaccinated people (e.g., for public health surveillance or the diagnosis of MIS-C or MIS-A), a test that specifically evaluates IgM/IgG to the nucleocapsid protein should be used.

Use of immune-based tests for tuberculosis infection, such as the tuberculin skin test and interferon-gamma release assay

COVID-19 vaccination should not be delayed because of testing for tuberculosis (TB) infection. Testing for TB infection with one of the immune-based methods, either the tuberculin skin test (TST) or an interferon release assay (IGRA), can be done before, after, or during the same encounter as COVID-19 vaccination.

TSTs and IGRAs were previously recommended to be administered ≥ 4 weeks after completion of COVID-19 vaccination to minimize potential theoretical interference between vaccination and TB testing. This was out of an abundance of caution during a period when these vaccines were new. However, given logistical challenges faced in delaying TB infection testing, the recommendation has been updated so that these tests may now be administered without regard to timing of COVID-19 vaccination.

Footnotes

1. The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the emergency use authorized formulation of Pfizer-BioNTech COVID-19 Vaccine for people aged 12 years and older (purple cap and label with purple border), when prepared according to their respective instructions for use, can

be used interchangeably . The Pfizer-BioNTech COVID-19 Vaccine supplied with an orange cap and a label with an orange border is authorized for use only in children aged 5-11 years. It is NOT interchangeable with COMIRNATY and Pfizer-BioNTech COVID-19 Vaccine for ages 12 years and older (purple cap and label with purple border).

2. 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"; e.g., a person who completed the second dose of a 2-dose primary series on April 1, 2021, can receive a booster dose as soon as October 1, 2021.
3. The 4-day grace period should not be used to prospectively schedule or administer a COVID-19 vaccine dose earlier than recommended.
4. WHO has listed the following COVID-19 vaccines for emergency use:
    - Pfizer-BioNTech COVID-19 Vaccines (e.g., COMIRNATY, Tozinameran)
    - AstraZeneca-Oxford COVID-19 Vaccines (e.g., Covishield, Vaxzevria)
    - Janssen (Johnson & Johnson) COVID-19 Vaccine
    - Moderna COVID-19 Vaccines (e.g., Takeda, Spikevax)
    - Sinopharm BIBP COVID-19 Vaccine
    - Sinovac-CoronaVac COVID-19 Vaccine
    - Bharat Biotech International COVID-19 Vaccine (COVAXIN)

    This list will be updated as additional COVID-19 vaccines receive an emergency use listing from WHO.

5. The Society of Breast Imaging has developed 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.
6. In a post-marketing observational study of people vaccinated with Shingrix (a vaccine for prevention of herpes zoster [shingles]), ~3-6 excess GBS cases per 1 million doses administered to persons ≥65 years in the 6 weeks after vaccination were observed. Although a causal relationship has not been established, FDA added a new warning about GBS in the Prescribing Information for Shingrix.

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Appendix A. Vaccine administration errors and deviations

A vaccine administration error is any preventable event that may cause or lead to inappropriate use of vaccine or patient harm. This appendix provides resources for preventing and reporting COVID-19 vaccine administration errors, as well as actions to take after an error has occurred. For completeness, this includes

additional scenarios that deviate from CDC recommendations for vaccine intervals but are not considered administration errors. This document is intended to assist vaccination providers with handling exceptional situations in which a vaccination error or deviation has already occurred and may be updated when additional information becomes available.

The recommendations in the table below apply to **all FDA-approved or FDA-authorized COVID-19 vaccines and all doses** (i.e., primary series, additional primary dose, booster dose), unless otherwise stated.

Currently, in most people, no more than 3 COVID-19 vaccine doses are recommended to be administered (see exceptions for certain moderately and severely immunocompromised people and recipients of hematopoietic cell transplant and CAR-T cell therapy. For a dose that is repeated due to an administration error (using the guidance in the table below), the dose given in error does not count toward the maximum number of doses. The repeated dose does count toward the 3-dose maximum.

The FDA-issued Fact Sheet for Healthcare Providers Administering Vaccines should be referenced for detailed information on storage and handling, dosing and schedule, dose preparation, and administration of COVID-19 vaccines. The information provided below on managing vaccine administration errors should not be interpreted as a recommendation or promotion of unauthorized use of the vaccines.

For all vaccine administration errors:

- Inform the recipient of the vaccine administration error.
- Consult with the state immunization program and/or immunization information system (IIS) to determine how the dose should be entered into the IIS, both as an administered dose and to account for inventory.
- Report the error to the Vaccine Adverse Event Reporting System (VAERS), unless otherwise indicated in the table. Providers are required to report all COVID-19 vaccine administration errors—even those not associated with an adverse event—to VAERS. To file an electronic report, please see the VAERS website .
- Determine how the error occurred and implement strategies to prevent it from happening again. A discussion on strategies to prevent errors can be found in the "Vaccine Administration" chapter of *Epidemiology and Prevention of Vaccine-Preventable Diseases* (Pink Book). Additional resources can be found on CDC's vaccine administration web page, including a job aid for preventing errors.

Table. Interim recommendations for COVID-19 vaccine administration errors and

deviations

Type	Administration error/deviation	Interim recommendation
Site/route	• Incorrect site (i.e., site other than the deltoid muscle [preferred site] or anterolateral thigh [alternate site])	• Do not repeat dose.*
	• Incorrect route (e.g., subcutaneous)	• Do not repeat dose.* Inform the recipient of the potential for local and systemic adverse events.
Age	• Unauthorized age group	• If received dose at age less than 5 years, do **not** give another dose at this time.∞ • If aged <18 years and the inappropriate Pfizer-BioNTech COVID-19 Vaccine formulation was administered, refer to the "Formulation and dosage" section below. • If aged 5–11 years and a vaccine other than a Pfizer-BioNTech COVID-19 Vaccine was inadvertently administered:§ ◦ If Moderna COVID-19 Vaccine administered as the first dose, it is suggested to give a single dose of the Pfizer-BioNTech COVID-19 Vaccine 5–11 years formulation (orange cap) as the second dose (at least 28 days after the Moderna COVID-19 Vaccine dose) because it is authorized in this age group. ◦ If Janssen COVID-19Vaccine administered, because the efficacy of this vaccine in people aged <18 years has not been established, a single dose of the Pfizer-BioNTech COVID-19 Vaccine 5–11 years formulation (orange cap) could be considered at least 2 months after the Janssen COVID-19 Vaccine. • If aged 12–17 years and a vaccine other than a Pfizer-BioNTech COVID-19 Vaccine was inadvertently administered: ◦ If Moderna COVID-19 Vaccine administered as the first dose, it is

		suggested to give Pfizer-BioNTech COVID-19 Vaccine ≥12 years formulation (purple cap)/COMIRNATY as the second dose (at least 28 days after the Moderna vaccine dose) because it is authorized in this age group. ◦ If Janssen COVID-19 Vaccine administered, because the efficacy of this vaccine in people aged <18 years has not been established, a single dose of the Pfizer-BioNTech COVID-19 Vaccine ≥12 years formulation (purple cap)/COMIRNATY could be considered at least 2 months after the Janssen COVID-19 Vaccine.
Formulation and dosage	• If aged 5–11 years and Pfizer-BioNTech COVID-19 Vaccine ≥12 years formulation (purple cap) /COMIRNATY inadvertently administered, resulting in a higher-than-authorized dose	• Do **not** repeat dose.[†] • If the dose given in error is the first dose, administer the second Pfizer-BioNTech COVID-19 Vaccine 5–11 years formulation (orange cap) dose 21 days later.[§]
	• If aged 12–17 years and administered the Pfizer-BioNTech Vaccine 5–11 years formulation (orange cap), resulting in a lower-than-authorized dose	• In general, do not repeat dose. However, based on clinical judgement (e.g., the adolescent received 2 doses of incorrect formulation), a repeat dose of Pfizer-BioNTech COVID-19 Vaccine ≥12 years formulation (30 µg, purple cap) may be administered at an interval of 21 days after the dose given in error. • If the dose given in error is the first dose, administer the Pfizer-BioNTech COVID-19 Vaccine ≥12 years formulation (30 µg, purple cap) dose 21 days after the last dose in order to complete the primary series.[§]
	• If aged ≥18 years and administered the Pfizer-BioNTech Vaccine 5–11 years formulation (orange cap), resulting in a lower-than-authorized dose	• **Repeat dose immediately** (no minimum interval) with the age-appropriate dose and formulation. If the dose given in error is the first dose, administer the second dose at the recommended interval after

		the repeat dose (i.e., 21 days after repeat dose) with the age-appropriate formulation.
	• Higher-than-authorized dose volume administered of the correct formulation	• Do **not** repeat dose.*† • Common errors may include: ◦ 0.5 mL administered for a Moderna COVID-19 Vaccine booster dose

	• Lower-than-authorized dose volume administered of the correct formulation (e.g., leaked out, equipment failure, recipient pulled away)	• **Repeat dose immediately** (no minimum interval).*
		• However, if a half-volume formulation of vaccine is administered on the same clinic day to a patient recommended for the full volume formulation, another half-volume dose can be administered, and the two doses can count as one full dose.
		• Common errors may include:
		  ◦ 0.25 mL administered for Moderna COVID-19 Vaccine primary series
		  ◦ 0.2 mL of Pfizer-BioNTech COVID-19 Vaccine ≥12 years formulation (purple cap)/ COMIRNATY administered to an individual ≥12 years.

Storage and handling	• Dose administered after improper storage and handling (i.e., temperature excursion)	• Contact the manufacturer for information on the stability of the vaccine. If the manufacturer does not have data to support the stability of the vaccine, repeat the dose immediately (no minimum interval).*
	• Dose administered past the expiration/beyond-use date	• Contact the manufacturer for information on the stability of the vaccine. If the manufacturer does not have data to support the stability of the vaccine, repeat the dose immediately (no minimum interval).*
Administration	• Dose administered within 90 days of anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma for COVID-19	• Do **not** repeat COVID-19 vaccine dose. If person is scheduled for a subsequent COVID-19 vaccine dose (e.g., second

	treatment	primary dose, additional primary dose, or booster dose), defer administration of subsequent dose for 90 days following receipt of antibody therapy. This deviation from CDC guidance does **not** require VAERS reporting.
	• Dose administered within 30 days of anti-SARS-CoV-2 monoclonal antibodies for post-exposure prophylaxis	• Do **not** repeat COVID-19 vaccine dose. If person is scheduled for a subsequent COVID-19 vaccine dose (e.g., second primary dose, additional primary dose, or booster dose), defer administration of subsequent dose for 30 days following receipt of antibody therapy. This deviation from CDC guidance does **not** require VAERS reporting.
Intervals	• Second mRNA COVID-19 vaccine dose administered fewer than 17 days (Pfizer-BioNTech COVID-19 Vaccine /COMIRNATY) or fewer than 24 days (Moderna COVID-19 vaccine) after the first mRNA COVID-19 vaccine dose (i.e., administered earlier than the 4-day grace period)	• Repeat dose.* The repeat dose should be spaced after the improperly spaced dose by the minimum interval (i.e., 21 days after the improperly spaced dose for the Pfizer-BioNTech COVID-19 Vaccine formulation/COMIRNATY and 28 days after the improperly spaced dose for the Moderna COVID-19 Vaccine).
	• The interval between the incorrect administration of an initial single dose of an mRNA COVID-19 vaccine (Pfizer-BioNTech COVID-19 Vaccine/COMIRNATY or Moderna COVID-19 Vaccine) and Janssen COVID-19 Vaccine is fewer than 24 days from the mRNA COVID-19 vaccine dose	• Do not administer a second primary dose of the mRNA COVID-19 vaccine.
	• Second dose of an mRNA COVID-19 vaccine (Pfizer-BioNTech COVID-19 Vaccine/COMIRNATY or Moderna COVID-19 Vaccine) administered at any interval **after** the recommended interval	• Do **not** repeat dose.* There is no maximum interval. This deviation from CDC guidance does **not** require VAERS reporting.
	• For people with moderate and severe immune compromise aged ≥12 years (Pfizer-BioNTech recipients) or ≥18 years	• Repeat dose.* The repeat dose should be spaced after the improperly spaced dose by the minimum interval (i.e., 28 days after

	(Moderna recipients), the additional primary dose (i.e., third dose) of an mRNA COVID-19 vaccine is administered fewer than 24 days after the second dose (i.e., administered earlier than the 4-day grace period)	the improperly spaced dose).
	• Any COVID-19 vaccine product is administered as a booster dose fewer than 6 months after a 2-dose primary mRNA COVID-19 vaccine series in a person who is not moderately or severely immunocompromised	• Do **not** repeat dose.
	• Any product is administered as a booster dose fewer than 2 months after 1 dose of Janssen COVID-19 primary vaccine	• Do **not** repeat dose.
Mixed series	• Incorrect mRNA COVID-19 vaccine product inadvertently administered as a second dose in 2-dose primary series or as an additional primary dose	• Do **not** repeat dose.*
Diluent (Pfizer-BioNTech COVID-19 Vaccine formulations/COMIRNATY only)	• ONLY diluent administered (i.e., sterile 0.9% sodium chloride)	• Administer the authorized dose immediately (no minimum interval).*
	• No diluent, resulting in higher than authorized dose (i.e., 0.3 ml of undiluted vaccine administered)	• Do **not** repeat dose*† Inform the recipient of the potential for local and systemic adverse events.
	• Incorrect diluent type (e.g., sterile water, bacteriostatic 0.9% NS)	• Contact the manufacturer for information on the stability of the vaccine. If the manufacturer does not have information to support the stability of the vaccine, repeat the dose immediately (no minimum interval).
	• Incorrect diluent volume	• If dilution results in a higher-than-authorized dose, do not repeat dose and inform the recipient of the potential for local and systemic adverse events.*† ◦ Pfizer-BioNTech COVID-19 Vaccine ≥12 years formulation (purple cap)/COMIRNATY: Applies to doses

		administered with diluent volume less than 1.8 mL ◦ Pfizer-BioNTech COVID-19 Vaccine 5–11 years formulation (orange cap): Applies to doses administered with diluent volume less than 1.3 mL • If dilution results in a lower-than-authorized dose, repeat dose immediately (no minimum interval).* ◦ Pfizer-BioNTech COVID-19 Vaccine ≥12 years formulation (purple cap)/COMIRNATY: Applies to doses administered with diluent volume greater than 1.8 mL ◦ Pfizer-BioNTech COVID-19 Vaccine 5–11 years formulation (orange cap): Applies to doses administered with diluent volume greater than 1.3 mL

*In the case of an error, providers should follow the Interim Recommendations in this table then continue with any subsequent doses according to the recommended schedule and intervals.

∞Do not administer the second dose until the person becomes eligible to receive vaccination (either by reaching the authorized age or if the authorization is extended to include additional age groups), even if this results in the second dose being administered after the recommended interval between doses.

†If the administration error resulted in a higher-than-authorized vaccine dose, in general the second dose may still be administered at the recommended interval. However, if local or systemic side effects following vaccination are clinically concerning (outside of the expected side effect profile), lead to serious adverse reactions, or are ongoing at the time of the second dose, the decision to administer the second dose may be assessed on a case-by-case basis.

§ Individuals who will turn from 11 years to 12 years of age between their first and second dose in the primary regimen may receive, for either dose, either: (1) the Pfizer-BioNTech COVID-19 Vaccine formulation authorized for use in individuals 5 through 11 years of age (each 0.2 mL dose containing 10 µg) (orange cap); or (2) COMIRNATY or the Pfizer-BioNTech COVID-19 Vaccine formulation authorized for use in individuals 12 years of age and older (each 0.3 mL dose containing 30 µg (purple cap). This dosing is in accordance with the FDA EUA and if such dosing occurred, this is not considered an error and VAERS reporting is not indicated.

Appendix B: Triage of people with a history of allergies or allergic reactions

CONTRAINDICATION TO COVID-19 VACCINATION	PRECAUTION TO COVID-19 VACCINATION	MAY PROCEED WITH COVID-19 VACCINATION
History of the following: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of a COVID-19 vaccine[1,2] • Known (diagnosed) allergy to a component of a COVID-19 vaccine[1]	**Among people without a contraindication, a history of:** • Any immediate allergic reaction[3] to other vaccines (non-COVID-19) or injectable therapies[4] • Non-severe, immediate (onset <4 hours) allergic reaction[2] after a previous dose of COVID-19 vaccine[6] Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 Vaccine, and vice versa[5]	**Among people without a contraindication or precaution, a history of:** • Allergy (including anaphylaxis) to oral medications (including the oral equivalent of an injectable medication) • History of food, pet, insect, venom, environmental, latex, etc., allergies, including anaphylaxis • Family history of allergies
Actions: • Do not vaccinate • Consider referral to allergist-immunologist • Consider other vaccine alternative if age appropriate[1,5]	**Actions:** • Risk assessment • 30-minute observation period if vaccinated (see footnotes 5 and 6 for information on vaccination setting) • Consider referral to allergist-immunologist	**Actions:** • 30-minute observation period: people with history of anaphylaxis (due to any cause) • 15-minute observation period: all other people

[1] See Appendix C for a list of ingredients. People with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna). However, some of these individuals may be able to receive Janssen COVID-19 Vaccine after a detailed risk assessment and possibly allergy testing (see footnote 5 below).

[2]Severe allergic reactions include

- Possible anaphylaxis, a progressive life-threatening reaction that typically includes urticaria but also with other symptoms such as wheezing, difficulty breathing, or low blood pressure (see Appendix D)
- Any angioedema affecting the airway (i.e., tongue, uvula, or larynx)
- Diffuse rash which also involves mucosal surfaces (e.g., Stevens-Johnson Syndrome)

Non-severe allergic reactions may include

- Urticaria (hives) beyond the injection site
- Angioedema (visible swelling) involving lips, facial skin, or skin in other locations. NOTE: Any angioedema affecting the airway (i.e., tongue, uvula, or larynx) would NOT be in this category and is considered a severe allergic reaction

[3] Immediate allergic reaction to a vaccine or injectable therapy is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

[4] People with a history of an immediate allergic reaction to a non-COVID-19 vaccine or injectable therapy that contains multiple components, one or more of which is a component of a COVID-19 vaccine, but it is unknown which component elicited the allergic reaction, have a precaution to vaccination with that COVID-19 vaccine. These individuals may benefit from consultation with an allergist-immunologist who can perform a more detailed risk assessment for COVID-19 vaccine receipt and possibly allergy testing.

[5] Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 Vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur. People with a contraindication to mRNA COVID-19 vaccines (including due to a known allergy to PEG) have a precaution to Janssen COVID-19 Vaccine. Among people who received a first mRNA COVID-19 dose but for whom the second dose is contraindicated, consideration may be given to vaccination with Janssen COVID-19 Vaccine (administered at least 28 days after the mRNA COVID-19 dose). People with a contraindication to Janssen COVID-19 Vaccine (including due to a known allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines. For people with these precautions, referral to an allergist-immunologist should be considered. Healthcare professionals and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project. In patients with these precautions, vaccination should only be undertaken in an appropriate setting under the supervision of a healthcare professional experienced in the management of severe allergic reactions.

[6] For people with a history of an immediate, non-severe allergic reaction after an mRNA COVID-19 vaccine, vaccination with a subsequent dose of either of the mRNA COVID-19 vaccines should only be undertaken

in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Similarly, for people with a history of an immediate, non-severe allergic reaction after Janssen COVID-19 Vaccine, vaccination with a subsequent dose of Janssen vaccine should only be undertaken under the supervision of a health care provider experienced in the management of severe allergic reactions. Administering the other vaccine type is another option; this can be done with a 30-minute observation period in a usual COVID-19 vaccination setting.

Appendix C: Ingredients included in COVID-19 vaccines

The following is a list of ingredients for the Pfizer-BioNTech , Moderna , and Janssen COVID-19 Vaccines reported in the prescribing information for each vaccine.*

Description	Pfizer-BioNTech (mRNA) For persons aged 5-11 years (10 µg dose) formulation	Pfizer-BioNTech (mRNA) For persons aged ≥12 years (30 µg dose) formulation	Moderna (mRNA) For persons aged ≥18 years	Janssen (viral vector) For persons aged ≥18 years
Active ingredient	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein
Inactive ingredients	2[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide	2[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide	PEG2000-DMG:1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol	Polysorbate-80
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	2-hydroxypropyl-β-
	Cholesterol	Cholesterol	Cholesterol	Citric acid monohydrate
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102:heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate	Trisodium citrate dihydrate

Tromethamine	Sodium chloride	Tromethamine	Sodium chloride
Tromethamine hydrochloride	Monobasic potassium phosphate	Tromethamine hydrochloride	Ethanol
Sucrose	Potassium chloride	Acetic acid	
	Dibasic sodium phosphate dihydrate	Sodium acetate	
	Sucrose	Sucrose	

* None of the vaccines contain eggs, gelatin, latex, or preservatives. All COVID-19 vaccines are **free from metals** such as iron, nickel, cobalt, lithium, rare earth alloys or any manufactured products such as microelectronics, electrodes, carbon nanotubes, or nanowire semiconductors.
Note: Both the Pfizer-BioNTech and Moderna COVID-19 vaccines contain polyethylene glycol (PEG). PEG is a primary ingredient in osmotic laxatives and oral bowel preparations for colonoscopy procedures, an inactive ingredient or excipient in many medications, and is used in a process called "pegylation" to improve the therapeutic activity of some medications (including certain chemotherapeutics). Additionally, cross-reactive hypersensitivity between PEG and polysorbates (included as an excipient in some vaccines and other therapeutic agents) can occur. Information on active or inactive ingredients for vaccines and medications can be found in the package insert. CDC's vaccine excipient summary and the National Institutes of Health DailyMed database can also be used as a resource.

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

In patients who experience post-vaccination symptoms, determining the etiology (including allergic reaction, vasovagal reaction, or vaccine side effects) is important to determine whether a person can receive further doses of the vaccine. The following table of signs and symptoms is meant to serve as a resource but might not be exhaustive, and patients might not have all signs or symptoms. Vaccination providers should use their clinical judgement when assessing patients to determine the diagnosis and management.

Characteristic	Allergic reactions (including anaphylaxis)	Vasovagal reaction	Vaccine side effects (local and systemic)
Timing after vaccination	Most occur within 15-30 minutes of vaccination	Most occur within 15 minutes	Median of 1 to 3 days after vaccination (with most occurring the day

			after vaccination)
Signs and symptoms			
Constitutional	Feeling of impending doom	Feeling warm or cold	Fever, chills, fatigue
Cutaneous	Skin symptoms present in ~90% of people with anaphylaxis, including pruritus, urticaria, flushing, angioedema	Pallor, diaphoresis, clammy skin, sensation of facial warmth	Pain, erythema, or swelling at injection site; lymphadenopathy in same arm as vaccination
Neurologic	Confusion, disorientation, dizziness, lightheadedness, weakness, loss of consciousness	Dizziness, lightheadedness, syncope (often after prodromal symptoms for a few seconds or minutes), weakness, changes in vision (such as spots of flickering lights, tunnel vision), changes in hearing	Headache
Respiratory	Shortness of breath, wheezing, bronchospasm, stridor, hypoxia	Variable; if accompanied by anxiety, might have an elevated respiratory rate	N/A
Cardiovascular	Hypotension, tachycardia	Variable; might have hypotension or bradycardia during syncopal event	N/A
Gastrointestinal	Nausea, vomiting, abdominal cramps, diarrhea	Nausea, vomiting	Vomiting or diarrhea might occur
Musculoskeletal	N/A	N/A	Myalgia, arthralgia
Vaccine and clinical management recommendations			
Can receive a subsequent dose of COVID-19 vaccine?	See Appendix B	Yes	Yes

Note: Severe allergic reactions include:

- Possible anaphylaxis, a progressive life-threatening reaction that typically includes urticaria but also with other symptoms such as wheezing, difficulty breathing, or low blood pressure
- Any angioedema affecting the airway (i.e., tongue, uvula, or larynx)
- Diffuse rash which also involves mucosal surfaces (e.g., Stevens-Johnson Syndrome)

Non-severe allergic reactions may include:

- Urticaria (hives) beyond the injection site
- Angioedema (visible swelling) involving lips, facial skin, or skin in other locations. NOTE: Any angioedema affecting the airway (i.e., tongue, uvula, or larynx) would NOT be in this category and is

considered a severe allergic reaction

References

- The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine — United States, December 2020
- The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Moderna COVID-19 Vaccine — United States, December 2020
- The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID-19 Vaccine — United States, February 2021
- Updated Recommendations from the Advisory Committee on Immunization Practices for Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients—United States, April 2021
- The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Adolescents Aged 12–15 years — United States, May 2021
- Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021
- Use of COVID-19 Vaccines After Reports of Adverse Events Among Adult Recipients of Janssen (Johnson & Johnson) and mRNA COVID-19 Vaccines (Pfizer-BioNTech and Moderna): Update from the Advisory Committee on Immunization Practices — United States, July 2021
- Use of Pfizer-BioNTech COVID-19 Vaccine in Persons Aged ≥16 Years: Recommendations of the Advisory Committee on Immunization Practices — United States, September 2021
- The Advisory Committee on Immunization Practices' Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines — United States, 2021
- Pfizer-BioNTech COVID-19 Vaccine Fact Sheet for Healthcare Providers (fda.gov)
- Moderna COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers (fda.gov)
- Janssen COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers (fda.gov)
- ACIP General Best Practice Guidelines for Immunization
- Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination

Previous Updates:

October 25, 2021

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

September 27, 2021

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

September 15, 2021

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

August 31, 2021

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

August 25, 2021

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

August 13, 2021

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

August 11, 2021

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

August 6, 2021

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

July 16, 2021

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

July 2, 2021

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

June 1, 2021

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

years in patient counseling section.

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

May 14, 2021

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

April 27, 2021

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

medical conditions.

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

April 16, 2021

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

March 5, 2021

- Public health recommendations for vaccinated people have been moved to: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html.

March 3, 2021

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

February 10, 2021

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

of which is PEG, another mRNA vaccine component or polysorbate, but in whom it is unknown which component elicited the immediate allergic reaction have a precaution to vaccination.

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

Page last reviewed: November 5, 2021

COVID-19 Vaccination

Product Info by U.S. Vaccine

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Managing Anaphylaxis

Myocarditis and Pericarditis Considerations

Lab Tests After Severe Allergic Reactions

Clinical Care

Provider Requirements and Support

Training and Education

Vaccine Recipient Education

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