Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States

Reference Materials

- Summary Document for Interim Clinical Considerations
- Interim COVID-19 Immunization Schedule for Ages 5+
- COVID-19 Vaccine Administration Error Revaccination Guidance
- COVID-19 Vaccine Administration Error Revaccination Guidance – Poster
- COVID-19 Vaccine Administration Errors Revaccination Guidance Checklist

Get Email Updates

To receive email updates about this page, enter your email address:

Email Address

What's this?

Submit

Summary of recent changes (last updated February 22, 2022):

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

Key points

- COVID-19 vaccines currently approved or authorized by FDA are effective in preventing serious outcomes of coronavirus disease 2019 (COVID-19), including severe disease, hospitalization, and death.
- COVID-19 primary series vaccination is recommended for everyone ages 5 years and older in the United States for the prevention of COVID-19.
- A 3-dose primary mRNA COVID-19 vaccine series is recommended for people ages 5 years and older who are moderately or severely immunocompromised, followed by a booster dose in those ages 12 years and older.
- In most situations, Pfizer-BioNTech or Moderna COVID-19 Vaccines are preferred over the Janssen COVID-19 Vaccine for primary and booster vaccination.
- A booster dose of COVID-19 vaccine is recommended for everyone ages 12 years and older. Timing of a booster dose varies based on COVID-19 vaccine product and immunocompetence.
- Efforts to increase the number of people in the United States who are up to date with their COVID-19 vaccines remain critical to preventing illness, hospitalizations and deaths from COVID-19.
- 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, Emergency Use Instructions (EUI) for FDA-approved 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. Additional vaccine product-specific information is also available.

COVID-19 vaccines

Three COVID-19 vaccines are currently approved under a BLA or authorized under an EUA by FDA (Table 1):

- Pfizer-BioNTech COVID-19 Vaccine/COMIRNATY (hereafter referred to as Pfizer-BioNTech in this document)[1]
- Moderna COVID-19 Vaccine/SPIKEVAX (hereafter referred to as Moderna in this document)[2]
- Janssen (Johnson & Johnson) COVID-19 Vaccine

For primary and booster vaccination for all populations, an mRNA COVID-19 vaccine series is preferred over the Janssen COVID-19 Vaccine. The mRNA COVID-19 vaccines are feasible for use in most vaccine-eligible populations or settings. However, offering the Janssen COVID-19 Vaccine is preferable to not providing any COVID-19 vaccine.

The Pfizer-BioNTech and Moderna vaccines are lipid nanoparticle-formulated, nucleoside-modified mRNA vaccines encoding the prefusion spike glycoprotein of SARS-CoV-2, the virus that causes COVID-19. The Janssen COVID-19 Vaccine is a recombinant, replication-incompetent adenovirus type 26 (Ad26) vector encoding the stabilized prefusion spike glycoprotein of SARS-CoV-2. None of the currently FDA-approved or FDA-authorized COVID-19 vaccines are live-virus vaccines.

TABLE 1. COVID-19 vaccine formulations currently approved or authorized in the United States

Vaccine manufacturer	Age indication	Vaccine vial cap color	Dilution required	Primary Series		Booster dose	
				Dose	Injection volume	Dose	Injection volume
Pfizer-BioNTech	5–11 years	Orange	Yes	10 µg	0.2 mL	NA	NA
Pfizer-BioNTech	≥12 years	Purple	Yes	30 µg	0.3 mL	30 µg	0.3 mL
Pfizer-BioNTech	≥12 years	Gray	No	30 µg	0.3 mL	30 µg	0.3 mL
Moderna	≥18 years	NA	No	100 µg	0.5 mL	50 µg	0.25 mL
Janssen	≥18 years	NA	No	5×10^{10} viral particles	0.5 mL	5×10^{10} viral particles	0.5 mL

For information on the formulations, storage and handling, preparation, and administration of COVID-19 vaccines, see U.S. COVID-19 Vaccine Product Information.

Box 1. 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.

Emergency Use Instructions (EUI): Provision of the 2013 Pandemic and All-Hazards Preparedness Reauthorization Act which gives CDC legal authority to create and issue EUI to permit emergency use of FDA-approved medical products. The EUI consist of Fact Sheets to inform healthcare providers and recipients about such products' approved, licensed, or

cleared conditions of use, and may provide information about emergency use of FDA-approved medical products that is not included in or differs in some way from the information provided in the FDA-approved labeling (package insert).

Groups recommended for vaccination

COVID-19 vaccination is recommended for everyone ages 5 years and older in the United States for the prevention of COVID-19. The age groups approved under BLA or authorized under EUA to receive vaccination vary by vaccine product. CDC recommends that people get up to date with COVID-19 vaccination as soon as feasible, which includes the completed primary series and any recommended booster doses.

COVID-19 vaccine use terminology, including for primary series vaccination and booster vaccination, is defined below (BOX 2).

There is currently no FDA-approved or FDA-authorized COVID-19 vaccine for children ages 4 years and younger. These children should not receive any COVID-19 vaccine doses (including partial doses of vaccine formulations approved or authorized for people ages 5 years and older) at this time unless part of a clinical trial.

See appendices E (People who received COVID-19 vaccine outside the United States) and F (People who received COVID-19 Vaccine as part of a clinical trial) for recommendations on these topics.

Box 2. Terminology for COVID-19 vaccine dosing

Primary series:

- For most people, 2-dose series of an mRNA COVID-19 vaccine (Pfizer-BioNTech and Moderna) or a single dose of Janssen Vaccine.
- For people who are moderately or severely immunocompromised, a 3-dose series of an mRNA COVID-19 vaccine or a single dose of Janssen COVID-19 Vaccine.

Additional dose: A subsequent dose of vaccine administered to people who likely did not mount a protective immune response after initial vaccination. People who are moderately or severely immunocompromised and who received Janssen COVID-19 Vaccine for their primary series should receive an additional dose.

Booster dose: A subsequent dose of vaccine administered to enhance or restore protection which might have waned over time after primary series vaccination.

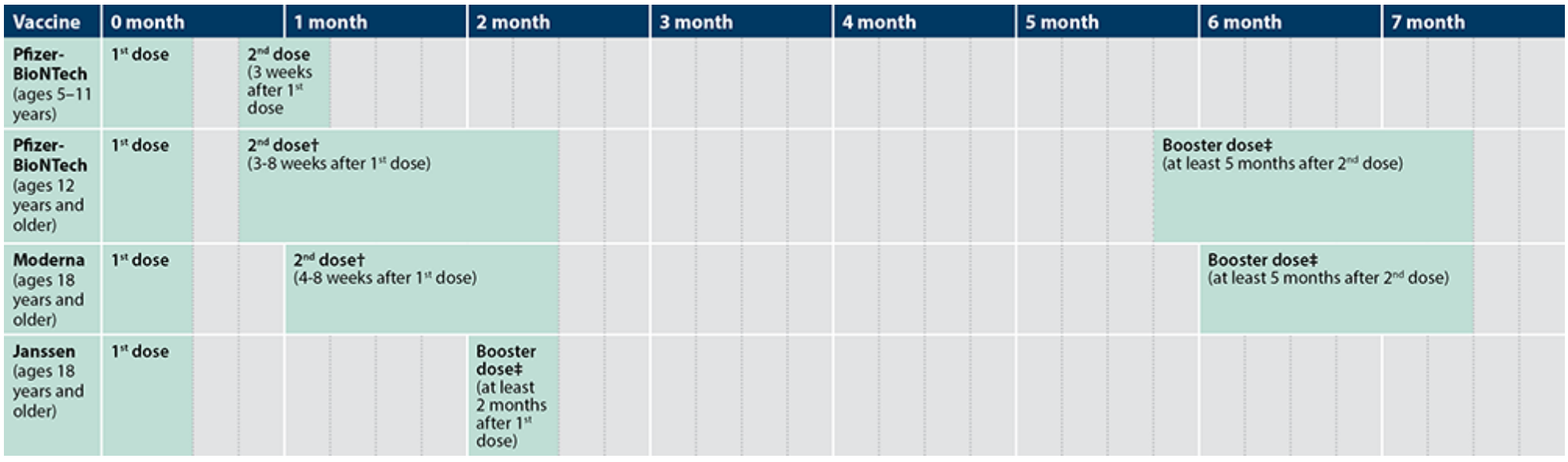
Homologous booster dose: The same vaccine product used for the booster dose was administered for the primary series.

Heterologous booster dose (mix-and-match booster): The vaccine product used for the booster dose differs from the product administered for the primary series Interim clinical considerations regarding the use of specific vaccines, dosage and administration, specific populations and situations, and contraindications and precautions are summarized in the sections that follow. 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) .

Up to date: All recommended primary vaccine series doses and booster doses for which a person is eligible have been received.

Primary series

COVID-19 Vaccination Schedule*



View Larger

Note: Timeline is approximate. Intervals of 3 months or fewer are converted into weeks per the formula "1 month = 4 weeks." Intervals of 4 months or more are converted into calendar months.

*See Guidance for COVID-19 vaccination for people who are moderately or severely immunocompromised for schedule for people who are moderately or severely immunocompromised.

†An 8-week interval may be optimal for some people ages 12 years and older, especially for males ages 12 to 39 years. A shorter interval (3 weeks for Pfizer-BioNTech; 4 weeks for Moderna) between the first and second doses remains the recommended interval for: people who are moderately or severely immunocompromised; adults ages 65 years and older; and others who need rapid protection due to increased concern about community transmission or risk of severe disease.

‡An mRNA COVID-19 vaccine is preferred over the Janssen COVID-19 Vaccine for booster vaccination of people ages 18 years and older. For people ages 12–17 years, only Pfizer-BioNTech can be used. People ages 5–11 years should not receive a booster dose.

mRNA COVID-19 vaccines

The mRNA COVID-19 vaccines are administered as a:

- 2-dose primary series for most people;
- 3-dose primary series for people who are moderately or severely immunocompromised (see Guidance for COVID-19 vaccination for people who are moderately or severely immunocompromised).

The same mRNA vaccine product should be used for all doses of the primary series (see Interchangeability of COVID-19 vaccine products).

TABLE 2. COVID-19 vaccination schedule for the primary series in the general population*

Primary series vaccine manufacturer	Age group	Number of doses in primary series	Number of booster doses	Interval between 1st and 2nd dose	Interval between primary series and booster dose
Pfizer-BioNTech	5–11 years	2	NA	3 weeks	NA
Pfizer-BioNTech	≥12 years	2	1	3-8 weeks†	≥5 months
Moderna	≥18 years	2	1	4-8 weeks†	≥5 months
Janssen	≥18 years	1	1	NA	≥2 months

*For the vaccination schedule for people who are moderately or severely immunocompromised, see Table 3

†An **8-week** interval may be optimal for some people ages 12 years and older, especially for males ages 12 to 39 years. A **shorter interval** (3 weeks for Pfizer-BioNTech; 4 weeks for Moderna) between the first and second doses remains the recommended interval for: people who are moderately to severely immunocompromised; adults ages 65 years and older; and others who need rapid protection due to increased concern about community transmission or risk of severe disease.

Pfizer-BioNTech COVID-19 Vaccine is FDA-approved or FDA-authorized in people ages 5 years and older as a 2-dose primary series, with an interval of 3 weeks between doses.

Vaccination providers should ensure the correct age-appropriate formulation is administered based on the recipient's age on the day of vaccination (Table 1).

Moderna COVID-19 Vaccine is FDA-approved or FDA-authorized in people ages 18 years and older as a 2-dose primary series, with an interval of 4 weeks between doses.

Considerations for intervals for mRNA COVID-19 vaccine primary series

mRNA COVID-19 vaccines are FDA-approved or authorized for a **3-week** (Pfizer-BioNTech vaccine) or **4-week** (Moderna vaccine) interval between the first and second dose. A 3- or 4-week interval continues to be the recommended interval for people who are moderately to severely immunocompromised, adults ages 65 years and older, and others who need rapid protection due to increased concern about community transmission or risk of severe disease. mRNA COVID-19 vaccines are safe and effective at the FDA-approved or FDA-authorized intervals, but a longer interval may be considered for some populations. While absolute risk remains small, the relative risk for myocarditis is higher for males ages 12-39 years, and this risk might be reduced by extending the interval between the first and second dose. Some studies in adolescents (ages 12-17 years) and adults have shown the small risk of myocarditis associated with mRNA COVID-19 vaccines might be reduced and peak antibody responses and vaccine effectiveness may be increased with an interval longer than 4 weeks. Extending the interval beyond 8 weeks has not been shown to provide additional benefit. There are currently no data available for children ages 11 years and younger. Therefore, an **8-week** interval may be optimal for **some people ages 12 years and older**, especially for males ages 12–39 years.

Janssen COVID-19 Vaccine

Although mRNA vaccines are preferentially recommended in most situations over the Janssen COVID-19 Vaccine, the Janssen COVID-19 Vaccine may be considered in some situations. See Considerations for Janssen COVID-19 Vaccine and Contraindications and precautions.

Janssen COVID-19 Vaccine is FDA-authorized for use in people ages 18 years and older. The primary series is a single primary dose. See Appendix B for additional information about completing schedules that have included use of the Janssen COVID-19 vaccine in people who are moderately or severely immunocompromised.

Booster dose

All people ages 12 years and older **should receive** an age-appropriate booster dose and formulation of COVID-19 vaccine (Table 2), even if they were age 11 years or younger at the time of the primary series. Currently, COVID-19 vaccines are not authorized for a booster dose for children ages 11 years and younger.

An mRNA COVID-19 vaccine is preferred over the Janssen COVID-19 Vaccine for booster vaccination. In people ages 12–17 years, only Pfizer-BioNTech COVID-19 Vaccine can be used.

Interval between primary series and booster doses[3]

The recommended interval for the booster dose is based on the product received for the primary series. In most people, the interval is:

- At least 5 months after mRNA 2-dose primary vaccination or
- At least 2 months after Janssen single dose primary vaccination

For information about schedules and booster doses for people who are moderately or severely immunocompromised, see guidance for COVID-19 vaccination for people who are moderately or severely immunocompromised.

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

People with immunocompromising conditions or people who take immunosuppressive medications or therapies are at increased risk for severe COVID-19. Because the immune response following COVID-19 vaccination may differ in moderately or severely immunocompromised people, specific guidance for this population is provided. **Use of mRNA vaccines is preferred.**

COVID-19 Vaccination Schedule for People Who Are Moderately or Severely Immunocompromised

Vaccine	0 month	1 month	2 month	3 month	4 month	5 month
Pfizer-BioNTech (ages 5–11 years)	1st dose	2nd dose (3 weeks after 1st dose)	3rd dose (at least 4 weeks after 2nd dose)			
Pfizer-BioNTech (ages 12 years and older)	1st dose	2nd dose (3 weeks after 1st dose)	3rd dose (at least 4 weeks after 2nd dose)		Booster dose* (at least 3 months after 3rd dose)	
Moderna (ages 18 years and older)	1st dose	2nd dose (4 weeks after 1st dose)	3rd dose (at least 4 weeks after 2nd dose)			Booster dose* (at least 3 months after 3rd dose)
Janssen (ages 18 years and older)	1st dose	2nd (additional) dose† using an **mRNA COVID-19 vaccine** (at least 4 weeks after 1st dose)		Booster dose* (at least 2 months after additional dose)		

View Larger

Note: Timeline is approximate. Intervals of 3 months or fewer are converted into weeks per the formula “1 month = 4 weeks”. Intervals of 4 months or more are converted into calendar months.

*An mRNA COVID-19 vaccine is preferred over the Janssen COVID-19 Vaccine for booster vaccination of people ages 18 years and older. For people ages 12–17 years, only Pfizer-BioNTech can be used. People ages 5–11 years should not receive a booster dose.

†Only Pfizer-BioNTech or Moderna COVID-19 Vaccine should be used. See Appendix B for more information on vaccinating people who are moderately or severely immunocompromised and who received Janssen COVID-19 Vaccine for the primary series.

Primary series for people with moderate or severe immunocompromise

mRNA COVID-19 vaccines

A **3-dose primary series** is recommended for people ages 5 years and older who are moderately or severely immunocompromised **at the time of vaccination** (Table 3). The same mRNA vaccine product should be used for all doses of the primary series (see Interchangeability of COVID-19 vaccine products).

Pfizer-BioNTech COVID-19 Vaccine (5 years and older): The second dose is administered 3 weeks after the first dose; the third dose is administered at least 4 weeks after the second dose.

Moderna COVID-19 Vaccine (18 years and older): The second dose is administered 4 weeks after the first dose; the third dose is administered at least 4 weeks after the second dose. The dose is 100 µg (0.5 ml) for all doses in the primary series.

Janssen COVID-19 Vaccine

A **primary Janssen vaccine dose** is recommended for people ages 18 years and older who are moderately or severely immunocompromised, followed by a **second (additional) dose using an mRNA COVID-19 vaccine** at least 4 weeks later (see Appendix B for additional information). If Moderna COVID-19 vaccine is used for the second dose, administer a 100 µg (0.5 ml) dose.

Booster doses for people with moderate or severe immunocompromise

Booster doses are recommended for people 12 years of age and older after completion of primary vaccination.

mRNA COVID-19 vaccine primary series

A single booster dose is recommended at least 3 months after the third dose in the primary series, **for a total of four doses**, preferably with an mRNA COVID-19 vaccine. If Moderna vaccine is used for the booster dose, a 50 µg (0.25 mL) dose should be used.

Janssen COVID-19 primary vaccination

A single booster dose is recommended at least **2 months** after the second (additional) dose, for a total of **3 doses** (1 Janssen vaccine dose followed by 1 additional mRNA vaccine dose, then 1 booster dose). mRNA vaccines are preferred for the booster dose. If the Moderna vaccine is used for the booster dose, a 50 µg (0.25 ml) dose should be used.

Special situation: Many recipients of Janssen COVID-19 Vaccine may have already received a booster dose (Pfizer-BioNTech, Moderna [50 µg, 0.25 ml], or Janssen vaccine), without having had the second (additional) mRNA vaccine dose. In this situation, regardless of type and timing of vaccine received as the second dose, administer a Pfizer-BioNTech vaccine or a Moderna vaccine (100 µg [0.5 mL]) as the third dose at least 2 months after dose 2. See Appendix B for additional dose information for Janssen COVID-19 Vaccine recipients.

Table 3: COVID-19 vaccination schedule for people with moderate or severe immunocompromise*

Primary vaccination	Age group	Number of primary vaccine doses	Number of booster doses	Interval between 1st and 2nd dose	Interval between 2nd and 3rd dose	Interval between 3rd and 4th dose
Pfizer-BioNTech	5–11 years	3	NA	3 weeks	≥4 weeks	N/A
Pfizer-BioNTech	≥12 years	3	1	3 weeks	≥4 weeks	≥3 months
Moderna	≥18 years	3	1	4 weeks	≥4 weeks	≥3 months
Janssen	≥18 years	1 Janssen, followed by 1 mRNA	1	4 weeks	≥2 months	N/A

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 chimeric antigen receptor (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 a third primary dose for people who are not moderately or severely immunocompromised is currently unknown.

Considerations for COVID-19 revaccination

Revaccination is defined as repeating a dose(s) of vaccine. Recipients of HCT or CAR-T-cell therapy who received one or more doses of COVID-19 vaccine prior to or during treatment should be revaccinated (i.e., complete primary vaccination and any recommended additional or booster doses) for any dose(s) received before or during treatment. Any revaccination doses should be given with an mRNA vaccine, regardless of vaccine administered for initial vaccination, and should start at least 3 months (12 weeks) after transplant or CAR-T-cell therapy. A patient's clinical team is best positioned to determine the degree of immune compromise, need for revaccination, and appropriate timing of revaccination.

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

Whenever possible, COVID-19 vaccines should be administered at least 2 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.

The utility of serologic testing or cellular immune testing to assess immune response to vaccination and guide clinical care has not been established. Serologic testing or cellular immune testing outside of the context of research studies is **not recommended at this time.**

Additional considerations

People can self-attest to their moderately to severely immunocompromised status and receive COVID-19 vaccine doses wherever vaccines are offered. Vaccinators should not deny COVID-19 vaccination to a person due to lack of documentation.

On a case-by-case basis, providers of moderately or severely immunocompromised patients may administer mRNA COVID-19 vaccines outside of the FDA and CDC dosing intervals based on clinical judgment when the benefits of vaccination are deemed to outweigh the potential and unknown risks for the recipient. However, providers should not routinely administer additional doses of COVID-19 vaccine beyond those recommended in this guidance. Providers should consult treatment guidelines for use of monoclonal antibodies as pre-exposure prophylaxis for moderately or severely immunocompromised people who may not mount an immune response to COVID-19 vaccination.

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.

Vaccinated people who are immunocompromised should be counseled about the potential for a reduced immune response to COVID-19 vaccines. They and their close contacts should continue to follow current prevention measures.

4-Day Grace Period

Doses administered up to 4 days before the minimum interval, known as the 4-day grace period, are considered valid. If a dose is administered prior to the 4-day grace period and is a:

- Primary series dose, it **should** be repeated; the repeat dose should be spaced from the date of the dose given in error by the recommended minimum interval.
- Booster dose; it should **not** be repeated (see Appendix A for more details).

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

Interchangeability of COVID-19 vaccine products

In general, **the same mRNA vaccine product** (i.e., the same manufacturer) should be used for all doses in the primary series.

For people ages 18 years and older, 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 primary vaccination series.

In limited, exceptional situations where a person 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 age 18 years or older. 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 primary series.

Any product can be used for a booster dose (i.e., heterologous booster dose), for those ages 18 years and older. Only Pfizer-BioNTech COVID-19 Vaccine can be used for people ages 12-17 years old.

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.**

Best practices for multiple injections include:

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

See ACIP's general best practices and *Epidemiology and Prevention of Vaccine-Preventable Diseases* (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 ages 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 and booster doses. This recommendation also applies to people who experience SARS-CoV-2 infection before or after receiving any COVID-19 dose.

People with known current SARS-CoV-2 infection should defer any COVID-19 vaccination, including booster vaccination, at least until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met. Current evidence demonstrates a robust immune response to vaccination after infection, but information is lacking about whether and how the amount of time since infection affects the immune response to vaccination.

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

People 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 people 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 the protection might last.

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 in people who have had MIS-C or MIS-A from SARS-CoV-2 infection who have not yet received COVID-19 vaccine.

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 risk 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-2or 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 from SARS-CoV-2 infection who have not yet received COVID-19 vaccine who do not meet all the above criteria or for people with a history of MIS-A from SARS-CoV-2 infection who have not yet received COVID-19 vaccine. 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 a person develops MIS-C, MIS-A, or a similar clinical illness after receipt of a COVID-19 vaccine, referral to a specialist in infectious diseases, rheumatology, and/or cardiology should be considered. These people 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. An illness consistent with MIS-C or MIS-A occurring in people who received any COVID-19 vaccine should be reported to VAERS.

People who received passive antibody products

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

However, in people who previously received a COVID-19 vaccine, administration of tixagevimab/cilgavimab (EVUSHELD™) for pre-exposure prophylaxis should be deferred for at least two weeks after vaccination, per the product EUA.

Vaccinating people with a known COVID-19 exposure or during COVID-19 outbreaks

COVID-19 vaccines are not recommended for post-exposure prophylaxis to prevent SARS-CoV-2 infection. Unvaccinated people who were close contacts of a person with SARS-CoV-2 infection should typically not seek vaccination until quarantine has ended; this is to reduce the risk of transmission to others (e.g., healthcare personnel, other clinic patients), because vaccination is not expected to prevent SARS-CoV-2 infection that could occur after the exposure for which the person is in quarantine, and to avoid confusion between vaccination side effects and symptoms of COVID-19.

In certain circumstances, to avoid missed opportunities for vaccination, vaccination during quarantine could be considered during outreach and contact tracing activities or at the time of post-exposure SARS-CoV-2 testing. Examples might include when people 1) are likely to have repeated SARS-CoV-2 exposures because they are unable to effectively quarantine (e.g., residing in a congregate or crowded setting or during outbreaks in their community), or, 2) will have limited access to vaccination after their quarantine period has ended, or, 3) are unlikely to otherwise seek vaccination after their quarantine period has ended. In such situations, the person recommended for quarantine can receive vaccination as long as 1) they do not have symptoms consistent with COVID-19 or current SARS-CoV-2 infection, and, 2) appropriate infection prevention and control procedures are employed during vaccination.

However, they should also be informed that vaccination may not prevent SARS-CoV-2 infection until 2 weeks after the primary series is completed, i.e., will not prevent them from getting COVID-19 from the current exposure but should help protect them from infection after future exposures. In addition, SARS-CoV-2 viral testing may be necessary to differentiate between common post-vaccination symptoms and symptoms of SARS-CoV-2 infection:

- People who develop signs and symptoms associated with COVID-19 (e.g., cough, shortness of breath, runny nose, sore throat, loss of taste or smell) should isolate and be evaluated for SARS-CoV-2 infection as soon as possible.

People who develop signs and symptoms that could be from either COVID-19 vaccination or SARS-CoV-2 infection (e.g., fever, fatigue, headache, myalgia) without typical COVID-19 symptoms described above, and are clinically stable, should isolate and, if symptoms do not improve by two days post-vaccination, be evaluated for SARS-CoV-2 infection.

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 future.

Pregnancy

Staying up to date with COVID-19 vaccinations is recommended for people who are pregnant. Although the overall risks are low, 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. Additionally, pregnancies affected by COVID-19 are at increased risk for preterm birth and stillbirths, and might be at increased risk for other complications.

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

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. Data on uptake of COVID-19 vaccination among pregnant people can be found on CDC's COVID Data Tracker.

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. Because clinical trials of COVID-19 vaccines did not include people who were lactating, 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 milk secretion. Recent reports have shown that the antibodies developed from mRNA COVID-19 vaccination received both during and after pregnancy 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

There is currently no evidence that any vaccines, including COVID-19 vaccines, cause fertility problems. 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.

Vaccination of children and adolescents

This section summarizes special considerations for COVID-19 vaccination of children and adolescents.

Dosing and formulation

Children should receive the age-appropriate vaccine formulation and follow the schedule based on their age on the day of vaccination, regardless of their size or weight (Table 1). Children ages 5–11 years should receive the 10 µg Pfizer-BioNTech COVID-19 Vaccine (orange cap) formulation and adolescents ages 12 years and older should receive the 30 µg Pfizer-BioNTech COVID-19 Vaccine (purple or gray cap) formulation.

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 or gray cap) formulation for their second dose. However, the FDA authorization allows children who will turn from age 11 years to 12 years between their first and second dose in the primary regimen to receive, for either dose: (1) the Pfizer-BioNTech COVID-19 Vaccine formulation for children ages 5–11 years (each 0.2 mL dose containing 10 µg in an orange cap vial); or (2) the Pfizer-BioNTech COVID-19 Vaccine formulation authorized for use in people ages 12 years and older (each 0.3 mL dose containing 30 µg in a purple cap or gray cap vial). If such dosing occurred, the child has completed their primary series. This is not considered an error and VAERS reporting is not indicated.

Myocarditis

Myocarditis is a rare, serious adverse event that has been reported primarily after receipt of the second dose of mRNA COVID-19 vaccines, with the highest risk currently observed in males ages 12–29 years. FDA has authorized and ACIP and CDC have recommended Pfizer-BioNTech vaccines in children ages 5–11 years and adolescents ages 12–17 years based on the determination that the benefits of COVID-19 vaccination outweigh risks in these populations. Extending the interval between the first and second mRNA vaccine dose to 8 weeks might reduce the risk. More information on myocarditis and COVID-19 vaccination can be found here.

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. They should be informed that mRNA vaccines are preferred over the Janssen COVID-19 Vaccine and that there is a risk of thrombosis with thrombocytopenia syndrome (TTS) following receipt of the Janssen COVID-19 Vaccine. Those who elect to receive the Janssen COVID-19 Vaccine should be informed about the risk and symptoms of TTS that can occur (typically in the 2 weeks after vaccination), as well as the need to seek immediate medical care should symptoms develop.

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[4] on the same side as the vaccinated arm has been observed following vaccination with mRNA COVID-19 vaccines.

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.

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; these medications should not be used prophylactically for the purposes of prevention of post-vaccination symptoms. However, in general, aspirin is **not recommended** for use in children and adolescents ages 17 years and younger as an antipyretic or analgesic due to the risk of Reye's syndrome.

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 may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine but, as with the general population, mRNA vaccines are preferred over the Janssen COVID-19 Vaccine. If people with these conditions are immunocompromised because of medications such as high-dose corticosteroids or biologic agents, they should consult Guidance for COVID-19 vaccination for people who are moderately or severely immunocompromised.

People with a history of Bell's palsy

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

People with a history of GBS

Guillain-Barré syndrome (GBS) is a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis. For people with a history of GBS, as with the general population, an mRNA COVID-19 vaccine is preferred over Janssen COVID-19. No increased risk of GBS has been identified with mRNA COVID-19 vaccines.

An elevated risk of GBS **after** receipt of the Janssen COVID-19 vaccine has been observed. A history of GBS is a precaution for receipt of the Janssen COVID-19 vaccine. For people with a history of GBS after Janssen COVID-19 Vaccine, see Considerations for Janssen COVID-19 Vaccine.

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. The swelling is temporary and resolves with medical treatment, including corticosteroid therapy. 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 is unlikely to impair development of a protective antibody response.

People undergoing testing for tuberculosis infection

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-gamma release assay (IGRA), can be done before, after, or during the same encounter as COVID-19 vaccination.

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

Post-vaccination symptoms

In clinical trials of Pfizer-BioNTech and Moderna COVID-19 vaccines in adults, 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.

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 ages 5–11 years compared with adolescents and young adults ages 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. Vaccine 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.

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

A rare risk for myocarditis and/or pericarditis has been observed following receipt of mRNA COVID-19 vaccines. Cases have occurred predominantly in males ages 12–29 years within the first week after receiving the second dose of an mRNA COVID-19 vaccine. Most patients have been hospitalized for short periods, with most achieving resolution of acute symptoms. Accumulating evidence from multiple sources suggests a higher risk for myocarditis following Moderna compared to Pfizer-BioNTech COVID-19 vaccination.

To date, data suggest the risk for myocarditis and/or pericarditis after mRNA COVID-19 booster doses in young adults appears lower than risk after the primary mRNA COVID-19 vaccine series. Cases of myocarditis among children aged 5–11 years after mRNA COVID-19 vaccine have been rarely reported, and it is not yet known if there is any increased risk for myocarditis or pericarditis after mRNA COVID-19 vaccination in this age group; monitoring is ongoing.

After reviewing available data on the risks and benefits, ACIP and CDC determined that the benefits (e.g., prevention of COVID-19 cases and its severe outcomes) outweigh the risks of myocarditis and pericarditis after receipt of mRNA COVID-19 vaccines for children , adolescents, and young adults.

People receiving mRNA COVID-19 vaccines, especially males ages 12–29 years, should be made aware of the rare risk of myocarditis and/or pericarditis following receipt of mRNA COVID-19 vaccines and the benefit of COVID-19 vaccination in reducing the risk of severe outcomes from COVID-19, including the possibility of cardiac sequelae. Counseling should include the need to seek care if symptoms of myocarditis or pericarditis, such as chest pain, shortness of breath, or tachycardia develop after vaccination, particularly in the week after vaccination. Extending the interval between the first and second mRNA vaccine dose to 8 weeks might reduce the risk.

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

Development of myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine is a precaution to a subsequent dose of any COVID-19 vaccine and subsequent doses should generally be avoided.

Until additional safety data are available, experts advise that people who develop myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine generally **should not** receive a subsequent dose of any COVID-19 vaccine. If after a risk assessment, the decision is made to receive a subsequent COVID-19 vaccine dose, the person should wait until at least after their episode of myocarditis or pericarditis has resolved (i.e., resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by patient's clinical team). For men ages 18 years and older who choose to receive a subsequent COVID-19 vaccine, some experts advise the use of Janssen COVID-19 Vaccine be considered instead of mRNA COVID-19 vaccines. These people should be aware of the risk of TTS. Considerations for subsequent vaccination may include:

- The myocarditis or pericarditis was considered unrelated to mRNA COVID-19 vaccination (e.g., due to SARS-CoV-2 or other viruses), especially if the myocarditis or pericarditis diagnosis occurred more than 3 weeks after the most recent dose of COVID-19 vaccine
- Personal risk of severe acute COVID-19 (e.g., age, underlying conditions)
- 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.

History of myocarditis or pericarditis prior to COVID-19 vaccination

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.

Considerations for Janssen COVID-19 Vaccine

Post-vaccination symptoms

In clinical trials of the 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 ages 18–59 years compared to people ages 60 years and older.

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. Although the condition is rare, currently available evidence supports a causal relationship between Janssen COVID-19 Vaccine and TTS. Cases of TTS, including deaths, following administration of the Janssen COVID-19 Vaccine have been reported in males and female, with the highest risk in females ages 30-49 years.

Based on an updated risk-benefit analysis, mRNA COVID-19 vaccines are preferred over the Janssen COVID-19 Vaccine for all vaccine-eligible people. Vaccine providers should start the mRNA COVID-19 vaccine series even if there is uncertainty about how the patient will receive their second dose; setting alone should not be a reason to offer the Janssen COVID-19 Vaccine.

However, the Janssen COVID-19 Vaccine may be offered in some situations as described below:

- When there is a contraindication to mRNA COVID-19 vaccines (e.g., severe allergic reaction after a previous dose or to a component of an mRNA COVID-19 vaccine)
- When a person would otherwise remain unvaccinated for COVID-19 due to limited access to mRNA COVID-19 vaccines
- When a person wants to receive the Janssen COVID-19 Vaccine despite the safety concerns identified

All people who elect to receive a Janssen COVID-19 Vaccine should be informed about the risk and symptoms of TTS that could occur after vaccination (typically within 2 weeks after receipt), the need to seek immediate medical care should such symptoms develop at any time, and the availability of mRNA COVID-19 vaccines instead of the Janssen COVID-19 Vaccine. This guidance applies to the both primary and booster doses of Janssen COVID-19 Vaccine. People should seek medical attention immediately if they develop any of the following symptoms:

- 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

It is contraindicated to administer Janssen COVID-19 Vaccine to people with a history of TTS following receipt of the Janssen COVID-19 Vaccine or any other adenovirus vector-based COVID-19 vaccines (e.g., AstraZeneca's COVID-19 Vaccine, which is not authorized or approved in the United States). These people should receive a dose of an mRNA COVID-19 vaccine as a booster at least 2 months following their dose of the Janssen COVID-19 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, and report any occurrence of TTS to VAERS.

People with a history of thrombosis or risk factors for thrombosis

Although the mechanism of TTS associated with the Janssen COVID-19 Vaccine is unclear, it appears to be similar to another rare immune-mediated syndrome, "spontaneous" heparin-induced thrombocytopenia (HIT).

People with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as spontaneous or classic HIT, should not receive Janssen COVID-19 Vaccine. These people should receive a currently FDA-approved or FDA-authorized mRNA COVID-19 vaccine.

Available evidence does not indicate that other thromboembolic conditions (e.g., inherited or acquired thrombophilia, pregnancy, hormonal contraception use) increase the risk of TTS.

Guillain-Barré syndrome (GBS)

Vaccine safety monitoring suggests an elevated risk of GBS after Janssen COVID-19 vaccination with proportionally more GBS cases observed after Janssen COVID-19 vaccination compared with mRNA COVID-19 vaccination. The highest risk has been observed in males ages 50-64 years, with symptoms of GBS beginning within 42 days after Janssen COVID-19 vaccination.

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

Development of GBS after receipt of Janssen COVID-19 Vaccine is a precaution for receiving subsequent dose(s) of the Janssen COVID-19 Vaccine. People who develop GBS within 6 weeks after receipt of Janssen COVID-19 Vaccine should not receive another dose of Janssen COVID-19 Vaccine. An mRNA COVID-19 vaccine should be used for any subsequent doses. Providers should also strongly consider using an mRNA COVID-19 vaccine for subsequent doses in people who had GBS onset beyond 6 weeks after receipt of Janssen COVID-19 Vaccine. Any occurrence of GBS following COVID-19 vaccination should be reported to VAERS.

Contraindications and precautions

CDC considers the following to be contraindications and precautions to vaccination with COVID-19 vaccines:

Table 4. Contraindications and recommended action(s)

Contraindication	Recommended Action(s)

Contraindication	Recommended Action(s)
History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine	Do not vaccinate with the same type of COVID-19 vaccine (i.e., mRNA or Janssen COVID-19 Vaccine). See Appendix C for actions and additional information.
History of a known diagnosed allergy to a component of the COVID-19 vaccine	
For the Janssen COVID-19 Vaccine, TTS following receipt of a previous Janssen COVID-19 Vaccine (or other COVID-19 vaccines not currently authorized in the United States that are based on adenovirus vectors, e.g., AstraZeneca)*	Do not vaccinate with Janssen COVID-19 Vaccine. See Considerations for Janssen COVID-19 Vaccine for additional information on vaccinating with an mRNA COVID-19 vaccine.

Precaution	Recommended Action(s)
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"])	The benefit of vaccination outweighs the risks for most people. See Appendix C for actions and additional information.
People with a history of a non-severe, immediate (onset less than 4 hours) allergic reaction after a dose of one type of COVID-19 vaccine (i.e., mRNA or Janssen) have a precaution to the **same type of COVID-19 vaccine**	
People with an allergy-related contraindication to one type of COVID-19 vaccine have a precaution to **the other type** of COVID-19 vaccine (e.g., people with a contraindication to an mRNA COVID-19 vaccine have a precaution to Janssen COVID-19 vaccine and vice versa).	
Moderate or severe illness, with or without fever	Defer vaccination until the illness has improved.
For mRNA COVID-19 vaccines, history of myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine	A subsequent dose of any COVID-19 vaccine should generally be avoided. See Considerations for mRNA COVID-19 vaccines: Pfizer-BioNTech and Moderna for additional considerations.
For Janssen COVID-19 Vaccine, a history of GBS†	See Considerations for Janssen COVID-19 Vaccine and Special populations for additional information.

***Additionally,** people with a history of an episode of immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as spontaneous or classic HIT, should not receive Janssen COVID-19 Vaccine. These people should receive an mRNA COVID-19 vaccine.

†People who develop GBS within 6 weeks after receipt of Janssen COVID-19 Vaccine should not receive another dose of Janssen COVID-19 Vaccine. These people should receive an mRNA COVID-19 vaccine.

An **immediate allergic reaction** to a vaccine or injectable therapy is defined as any hypersensitivity-related signs or symptoms such as urticaria (hives), angioedema (visible swelling), respiratory distress (e.g., wheezing, stridor), or anaphylaxis that **occurs within four hours following administration**.

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 C)
- 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 include:

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

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

See:

- Appendix C for triage of people with a history of allergies or allergic reactions
- Appendix D for a list of ingredients in COVID-19 vaccines
- Managing Anaphylaxis for information on allergic reactions, including severity of allergic reactions.

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

- Risk of exposure to SARS-CoV-2 virus (e.g., 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 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 people.
- Ability of the patient to be vaccinated in a setting where appropriate medical care is immediately available for anaphylaxis. For people with a contraindication due to allergy to one type of COVID-19 vaccines (e.g., mRNA vaccines), who are receiving another type (e.g., Janssen vaccine) and for people with an immediate, non-severe allergic reaction after a previous dose of COVID-19 vaccine who are receiving vaccination with a subsequent dose of that COVID-19 vaccine type, vaccination should only be undertaken in an appropriate setting under the supervision of a healthcare professional experienced in the management of severe allergic reactions. Consultation with an allergist-immunologist may help to clarify the risk assessment for these people.

Healthcare professionals and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project.

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 vaccine)
  - History of non-severe, immediate (onset within 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 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 immunity to SARS-CoV-2 following COVID-19 vaccination. If antibody testing was done, vaccination with the primary series, an additional dose, or a booster dose should be completed as recommended regardless of the antibody test result. SARS-CoV-2 antibody tests currently authorized under an EUA have variable performance characteristics and limitations. Furthermore, serologic correlates of protection have not been established and antibody testing does not evaluate the cellular immune response.

Screening testing and vaccination

Unvaccinated people who are being screened for SARS-CoV-2 infection (e.g., work, school, travel requirement) may be vaccinated at the time of screening if they do not have symptoms consistent with COVID-19.

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 antibody 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 detects IgM/IgG to the nucleocapsid protein should be used.

Possible false RPR reactivity following COVID-19 vaccines

FDA has reported that falsely reactive Rapid Plasma Reagin (RPR; non-treponemal) test results can occur with certain RPR tests for at least five months following COVID-19 vaccination in some people. Treponemal testing for syphilis such as *Treponema pallidum* particle agglutination (TP-PA) and treponemal immunoassays do not appear to be impacted by this issue.

Footnotes

1. COMIRNATY is the proprietary name for the product licensed under the Biologics License Application (BLA). The Pfizer-BioNTech COVID-19 Vaccine has been available since December 10, 2020 under an Emergency Use Authorization (EUA). The originally-authorized Pfizer-BioNTech COVID-19 Vaccine has the same formulation as COMIRNATY, and vials of the BLA-compliant vaccine may bear the name “Pfizer-BioNTech COVID-19 Vaccine.” The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the emergency use authorized formulations of Pfizer-BioNTech COVID-19 Vaccine for people ages 12 years and older (purple cap/label and gray cap/label), 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 ages 5-11 years. It is NOT interchangeable with COMIRNATY and Pfizer-BioNTech COVID-19 Vaccine for ages 12 years and older (purple cap/label and gray cap/label).

2. SPIKEVAX is the proprietary name for the product licensed under the Biologics License Application (BLA). The Moderna COVID-19 Vaccine has been available since December 18, 2020 under an Emergency Use Authorization (EUA). The originally-authorized Moderna COVID-19 Vaccine has the same formulation as SPIKEVAX. The FDA-approved SPIKEVAX (COVID-19 Vaccine, mRNA) and the emergency use authorized formulations of Moderna COVID-19 Vaccine for people ages 18 years and older, when prepared according to their respective instructions for use, can be used interchangeably .
3. 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 September 1, 2021, can receive a booster dose as soon as February 1, 2022 (5 months after completion of the primary series).
4. 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.

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.

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.
- Follow the revaccination guidance in the table below, using an age-appropriate COVID-19 vaccine and formulation. Then continue with the recommended schedule of subsequent dose(s) unless otherwise noted (see footnotes).
    - For doses recommended to be repeated, some experts suggest further delaying the repeated dose for 8 weeks after the invalid dose based on the potential for increased reactogenicity and the rare risk of myocarditis from mRNA COVID-19 vaccine, particularly in groups at increased risk for myocarditis (e.g., 12-29 year old males). Individual risk for COVID-19 and the likelihood for an adverse event following COVID-19 vaccination should be taken into consideration when recommending a longer interval.

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

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

Type	Administration error/deviation	Interim recommendation

Type	Administration error/deviation	Interim recommendation
Site/route	• Incorrect site (i.e., site other than the deltoid muscle or anterolateral thigh)	• 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 (recipients ages 5 years and younger)	• Do **not** give another dose at this time.*

	• Unauthorized age group (recipients ages 5–11 years)	• If Moderna COVID-19 Vaccine administered:
		  ◦ As the first dose, administer a single dose of the age-appropriate Pfizer-BioNTech COVID-19 Vaccine at least 28 days after the Moderna COVID-19 Vaccine dose.
		  ◦ As the second dose, or as both the first and second dose, the primary series is complete.
		• If Janssen COVID-19-Vaccine administered:
		  ◦ Because the efficacy of this vaccine in this age group has not been established, administer a single dose of the age-appropriate Pfizer-BioNTech COVID-19 Vaccine at least 28 days after the Janssen COVID-19 Vaccine.

	• Unauthorized age group (recipients ages 12–17 years)	• If Moderna COVID-19 Vaccine administered:
		  ◦ As the first dose, administer the age-appropriate Pfizer-BioNTech COVID-19 Vaccine as the second dose at least 28 days after the Moderna vaccine dose. Administer a Pfizer-BioNTech booster dose at least 5 months later.
		  ◦ As the second dose, or as both the first and second dose, the primary series is complete. Administer a Pfizer-BioNTech booster dose at least 5 months later.
		  ◦ As a booster dose, no more doses are indicated. The recipient is up to date.
		• If Janssen COVID-19 Vaccine administered
		  ◦ Because the efficacy of this vaccine in this age group has not been established, administer a single dose of the age-appropriate Pfizer-BioNTech COVID-19 Vaccine formulation at least 28 days after the Janssen COVID-19 Vaccine. Administer a Pfizer-BioNTech booster dose at least 5 months later.

Formulation and dosage	• If ages 5–11 years and Pfizer-BioNTech COVID-19 Vaccine ≥12 years formulation (purple or gray cap) inadvertently administered	• If 0.1 mL administered, in general, do **not** repeat dose. However, based on clinical judgement (e.g., child received 2 doses of incorrect formulation), a repeat dose of Pfizer-BioNTech COVID-19 Vaccine 5–11 years formulation (orange cap) may be administered at an interval of ≥21 days after the dose given in error. [§] • If >0.1 mL administered, resulting in a higher-than-authorized dose, do **not** repeat dose.[†]
	• If ages 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 ages ≥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.[§]
	• Higher-than-authorized dose volume administered of the correct formulation	• Do **not** repeat 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.
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). [§]

Type	Administration error/deviation	Interim recommendation
	• 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). [§]
Intervals[¶]	• An mRNA primary series dose administered prior to the recommended interval[#]	• Repeat dose after the dose given in error by at least the minimum interval (i.e., no sooner than 21 days if Pfizer-BioNTech or 28 days of Moderna).[§]
	• Booster dose administered prior to the recommended interval.	• Do **not** repeat dose.
	• Any COVID-19 vaccine dose 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.
	• Tixagevimab/cilgavimab (EVUSHELD™) administered less than 14 days after COVID-19 vaccination.	• In general, do **not** repeat dose. However, based on clinical judgement, a repeat dose of vaccine may be administered at an interval of at least 28 days after the dose of vaccine. [§]
Mixed series	• Incorrect mRNA COVID-19 vaccine product inadvertently administered as part of a 2- or 3-dose primary series	• Do **not** repeat dose.
Diluent (Pfizer-BioNTech COVID-19 Vaccine formulations only [purple cap and orange cap])	• 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). [§]
	• Vaccine is mixed with too little diluent	• Do **not** repeat dose. Inform the recipient of the potential for local and systemic adverse events.[†]
	• Vaccine is mixed with too much diluent	• **Repeat dose immediately** (no minimum interval). [§]
	• Single-use vial of diluent is used to mix multiple vials of vaccine	• Do **not** repeat dose. Inform patient of the potential for bacterial infection.
Diluent (Pfizer-BioNTech COVID-19 formulation that should not be mixed with diluent, i.e., gray cap)	• Vaccine is mixed with any diluent (i.e., any type or volume of diluent)	• 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).[§]

[*]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 a subsequent dose may still be administered at the recommended interval. However, if local or systemic side effects following vaccination are clinically concerning (outside of the expected side effect profile), lead to serious adverse reactions, or are ongoing at the time of the subsequent dose, this dose might be delayed, but this decision should be assessed on a case-by-case basis.

[‡] People who will turn from age 11 years to 12 years between their first and second dose in the primary regimen may receive, either: (1) the Pfizer-BioNTech COVID-19 Vaccine formulation authorized for use in people ages 5 through 11 years (each 0.2 mL dose containing 10 µg) (orange cap); or (2) the Pfizer-BioNTech COVID-19 Vaccine formulation authorized for use in people ages 12 years and older (each 0.3 mL dose containing 30 µg) (purple or gray 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.

[§]Some experts suggest further delaying the repeat dose for 8 weeks after the invalid dose based on the potential for increased reactogenicity and the rare risk of myocarditis from mRNA COVID-19 vaccine, particularly in groups at increased risk for myocarditis (e.g., 12-29 year old males). Individual risk for COVID-19 and the likelihood for an adverse event following vaccination should be taken into consideration when recommending a longer interval.

[¶]For the purpose of the public health definition of fully vaccinated, doses administered with an interval error prior to October 25, 2021 do not need to be repeated.

[#]Vaccine administered up to 4 days before the minimum interval may be counted and do not need to be repeated.

Appendix B. Guidance for People who are Moderately or Severely Immunocompromised and Vaccinated with Janssen COVID-19 Vaccine

COVID-19 Vaccination History	And	Then	Next Dose Due
1 dose	The dose was Janssen COVID-19 Vaccine	Administer a second dose (an additional mRNA vaccine) at least 28 days after the 1st dose. • Pfizer: 0.3mL, or • Moderna 0.5mL	Administer a booster dose at least 2 months after the 2nd dose.* • Pfizer: 0.3mL, or • Moderna 0.25mL, or • Janssen: 0.5mL (mRNA is preferred over Janssen)
2 doses	Both doses are Janssen COVID-19 Vaccine	Administer a third dose (additional mRNA vaccine) at least 2 months after the 2nd dose. • Pfizer: 0.3mL, or • Moderna 0.5mL	Vaccination series complete; no additional vaccinations needed.
	1 dose of Janssen COVID-19 Vaccine and 1 dose of an mRNA COVID-19 Vaccine (given as booster dose, i.e., Pfizer 0.3mL or Moderna 0.25mL)[+]	Administer a third dose (additional mRNA vaccine) at least 2 months after the 2nd dose. • Pfizer: 0.3mL, or • Moderna 0.5mL	Vaccination series complete; no additional vaccinations needed.
	1 dose of Janssen COVID-19 Vaccine and 1 dose of an mRNA COVID-19 Vaccine (given as additional dose, i.e., Pfizer 0.3mL or Moderna 0.5mL)[+]	Administer a booster dose of any COVID-19 vaccine 2 months after the 2nd dose. • Pfizer: 0.3mL, or • Moderna 0.25mL, or • Janssen: 0.5mL (mRNA is preferred over Janssen)	Vaccination series complete; no additional vaccinations needed.

*mRNA vaccines are preferred.
[+]When reviewing vaccination history, doses of the Moderna COVID-19 Vaccine received prior to February 7, 2022 should be considered to have been the booster dosage (0.25 mL; 50 µg).

Appendix C: 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* [†] • Known (diagnosed) allergy to a component of a COVID-19 vaccine[*]	Among people without a contraindication, a history of: • Any immediate allergic reaction[‡] to other vaccines (non-COVID-19) or injectable therapies[§] • Non-severe, immediate (onset <4 hours) allergic reaction[†] after a previous dose of COVID-19 vaccine[#] Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 Vaccine, and vice versa[¶]	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

CONTRAINDICATION TO COVID-19 VACCINATION	PRECAUTION TO COVID-19 VACCINATION	MAY PROCEED WITH COVID-19 VACCINATION
Actions: • Do not vaccinate • Consider referral to allergist-immunologist • Consider other vaccine alternative if age appropriate*¶	**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

Note: This table is specific to allergy-related contraindications and precautions and is not inclusive of all COVID-19 vaccine contraindications and precautions.

* See Appendix D 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 people may be able to receive Janssen COVID-19 Vaccine after a detailed risk assessment and possibly allergy testing (see footnote ¶ below).

†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

‡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.

§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.

¶ 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.

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 D: 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 people ages 5-11 years (orange cap) and ≥12 years (gray cap) formulations	Pfizer-BioNTech (mRNA) For people ages ≥12 years (purple cap) formulation	Moderna (mRNA) For people ages ≥18 years	Janssen (viral vector) For people ages ≥18 years
Active ingredient	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 • 5–11 years (orange cap): 10 µg • 12 years and older (gray cap): 30 µg	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 (30 µg)	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-cyclodextrin
	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 E. People who received COVID-19 vaccine outside the United States

The recommendations for people vaccinated outside of the United States depend on the vaccine(s) received for the primary series, whether the primary series was completed, and whether a booster dose was received. People who initiated vaccination outside of the United States are considered to be up to date with their COVID-19 vaccines when they have completed the recommended actions described below.

For people who received all FDA-approved or -authorized COVID-19 vaccines, Pfizer-BioNTech COVID-19 Vaccine can be used in people ages 5 years and older and Moderna COVID-19 Vaccine can be used in people 18 years and older to complete vaccination.

For people who received **at least one COVID-19 vaccine that was not FDA-approved or -authorized**, Pfizer-BioNTech COVID-19 Vaccine can be used in people ages 12 years and older and Moderna COVID-19 Vaccine can be used in people ages 18 years and older to complete vaccination.*

Received a COVID-19 vaccine that is FDA-approved or FDA-authorized

Vaccination history	Recommended actions	Special situations
Received all recommended primary dose(s)	• Do not repeat primary series • Administer booster dose when eligible	People who are moderately or severely immunocompromised who: • Received 2 mRNA COVID-19 vaccine doses should receive a **third** mRNA primary dose followed by a booster dose, for a total of four vaccine doses • Received a Janssen COVID-19 Vaccine primary dose should receive one additional mRNA dose and one booster dose, for a total of three vaccine doses.
Received a partial 2-dose mRNA COVID-19 vaccine primary series	• Do not restart primary series • Complete primary series as close to the recommended time as possible, preferably with the same mRNA vaccine • Administer booster dose when eligible	• People vaccinated in countries where only a single mRNA dose is recommended in certain populations (e.g., people with a history of SARS-CoV-2 infection, adolescents) should complete the 2-dose primary mRNA series, and get a booster dose when eligible. • People who are moderately or severely immunocompromised who received 2 mRNA COVID-19 vaccine doses should receive a **third** mRNA primary dose followed by a booster dose for a total of four vaccine doses.
Received a booster dose after completion of primary series	Do not repeat booster dose	

Received a COVID-19 vaccine listed for emergency use by WHO but not approved or authorized by FDA*†

Vaccination history	Recommended actions	Special situations
Received all recommended primary doses for that vaccine	• Do not repeat primary series • Administer mRNA booster dose at least 5 months after last primary series dose	People ages 12 years and older who are moderately or severely immunocompromised should also receive: • A single dose of an mRNA COVID-19 vaccine at least 28 days after receiving the last dose of the non-FDA-approved or -authorized primary series. • An mRNA booster dose at least 3 months after last primary series dose, for a total of four vaccine doses.
Received partial primary series for that vaccine	• Administer a single dose of an mRNA COVID-19 vaccine at least 28 days after receipt of their first dose to complete primary series • Administer mRNA booster dose at least 5 months after last primary series dose	People ages 12 years and older who are moderately or severely immunocompromised should also receive: • A single dose of an mRNA COVID-19 vaccine at least 28 days after the last dose of the primary series. • An mRNA booster dose, at least 3 months after last primary series dose, for a total of four vaccine doses.
Received a booster dose after completion of primary series	Do not repeat booster dose	

Received a heterologous primary series composed of doses of a COVID-19 vaccine listed for emergency use by WHO, at least one of which is not FDA-approved or authorized*†

Vaccination history	Recommended actions	Special situations
Received two doses of vaccine	• Do not repeat primary series • Get mRNA booster dose at least 5 months after last primary series dose	People ages 12 years and older who are moderately or severely immunocompromised should receive: • A single dose of an mRNA COVID-19 Vaccine at least 28 days after receiving the last dose of the primary series. • An mRNA vaccine booster dose, at least 3 months after last primary series dose, for a total of 4 vaccine doses.
Received a booster dose after completion of primary series	Do not repeat the booster dose	

Received all or some of the recommended doses of COVID-19 vaccines that are NOT FDA-authorized, FDA-approved, or among those listed for emergency use by WHO

Vaccination history	Recommended actions	Special situations
Received any number and combination of vaccine doses	Doses received do not count toward vaccination in the US • Start primary series at least 28 days after the last dose of vaccine • Get mRNA booster dose at least 5 months after completion of primary series	People ages 12 years and older who are moderately or severely immunocompromised should restart the series, following guidance for this group around number and timing of primary series dose(s) and booster vaccination.

*The EUI provides a legal framework for heterologous use of mRNA COVID-19 vaccines (i.e., Pfizer-BioNTech and Moderna) in people who received a non-FDA authorized or approved COVID-19 vaccine outside of US.

†COVID-19 vaccines that are listed for emergency use by WHO that are not FDA-authorized or FDA-approved have not been evaluated for efficacy or safety by CDC or ACIP.

Appendix F. People who received COVID-19 vaccine as part of a clinical trial

Participants in clinical trials within or outside the United States who received all the recommended primary series doses of a WHO-EUL COVID-19 vaccine (i.e., not placebo) that is not FDA-approved or FDA-authorized are considered fully vaccinated. In addition, people who received a vaccine that is not listed for emergency use by WHO but for which a U.S. data and safety monitoring board or equivalent has independently confirmed efficacy are considered fully vaccinated; at this time, only the Moderna COVID-19 Vaccine in children ages 6–17 years and the Medicago COVID-19 Vaccine in people 18 years of age and older meets these criteria.

- Moderately or severely immunocompromised clinical trial participants should receive an additional dose of Pfizer-BioNTech COVID-19 Vaccine (ages 12 years and older) or Moderna COVID-19 Vaccine (ages 18 years and older) 28 days after receiving the second vaccine dose of a primary series as detailed in the Considerations for COVID-19 vaccination in moderately or severely immunocompromised people, unless they have received or plan to receive an additional or booster dose through a clinical trial.
- Clinical trial participants (including moderately or severely immunocompromised people who received a 3-dose primary series) **should** receive a single booster dose of Pfizer-BioNTech COVID-19 Vaccine (ages 12 years and older) or Moderna COVID-19 Vaccine (ages 18 years and older), unless they have received or plan to receive a booster dose through a clinical trial.

If clinical trial participants have questions about whether they should receive an additional and/or booster dose outside of the clinical trial, they should consult with their healthcare provider. Clinical trial participants who did not receive all the recommended doses, or who received other vaccines not listed above, should consult with their healthcare provider to determine if they should receive an FDA-approved or FDA-authorized COVID-19 vaccine series.

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
- The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Children Aged 5–11 Years — United States, November 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)
- Emergency Use Instructions for Healthcare Providers: Pfizer-BioNTech COVID-19 vaccine for Additional Primary and Booster Doses in Certain Persons Who Completed Primary Vaccination with Vaccines Not Approved/Authorized in the United States (cdc.gov)
- Emergency Use Instructions (EUI) Fact Sheet for Recipients and Caregivers: Pfizer-BioNTech COVID-19 vaccine for Additional Primary and Booster Doses in Certain Persons Who Completed Primary Vaccination with Vaccines Not Approved/Authorized in the United States (cdc.gov)
- ACIP General Best Practice Guidelines for Immunization
- Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination

Previous Updates:

February 11, 2022

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

January 6, 2022

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

December 23, 2021

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

December 17, 2021

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

December 10, 2021

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

November 19, 2021

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

November 17, 2021

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

November 3, 2021

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

October 25, 2021

- Updated guidance in section on Considerations for use of a COVID-19 booster dose.
- New section added on Overview of COVID-19 vaccines recommendations.
- Updated guidance in section on COVID-19 vaccine dosage and schedule.
- Updated guidance in section on People vaccinated for prevention of COVID-19 outside the United States.

- Updated guidance in section on COVID-19 vaccination and SARS-CoV-2 infection for People with prior or current SARS-CoV-2 infection; People with a history of multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A); People who received passive antibody products; and Vaccinated people who subsequently develop COVID-19.
- New guidance on Considerations for COVID-19 revaccination in the section on Considerations for COVID-19 vaccination in moderately and severely immunocompromised people.
- Updated Table in Appendix A: Vaccine administration errors and deviations.

September 27, 2021

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

September 15, 2021

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

August 31, 2021

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

August 25, 2021

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

August 13, 2021

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

August 11, 2021

- Updated considerations for 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: March 2, 2022