Centers for Disease Control and Prevention

Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendices, References, and Previous Updates

Summary of recent changes (last updated October 19, 2022):

- Guidance for use of a monovalent Novavax COVID-19 booster dose in people ages 18 years and older in limited situations

Appendices

Appendix A. Guidance for use of Janssen COVID-19 Vaccine

Janssen COVID-19 Vaccine is authorized for adults ages 18 years and older for the primary series dose and 1 booster dose in certain limited situations due to the risk of thrombosis with thrombocytopenia syndrome (TTS) following receipt of the vaccine:

- When there is a contraindication to mRNA (i.e., Moderna or Pfizer-BioNTech) and Novavax COVID-19 vaccines (e.g., severe allergic reaction after a previous dose or to a component of an mRNA COVID-19 vaccine) (see Table 4)
- When a person would otherwise remain unvaccinated for COVID-19 due to limited access to other COVID-19 vaccines
- When a person wants to receive Janssen COVID-19 Vaccine despite the safety concerns identified

COVID-19 vaccine recipients should be informed that Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines are recommended over Janssen COVID-19 Vaccine. People who elect to receive Janssen COVID-19 Vaccine should be informed about the risk and symptoms of TTS (see below), as well as the need to seek immediate medical care should symptoms develop.

Vaccination schedule

People who are not moderately or severely immunocompromised

- Adults ages 18 years and older are recommended to receive 1 primary dose and 1 booster dose at least 2 months after the primary dose. A bivalent mRNA booster dose is recommended.

People who are moderately or severely immunocompromised

- Adults ages 18 years and older are recommended to receive 1 primary dose, a second (additional) dose using a monovalent mRNA COVID-19 vaccine, and 1 booster dose; a bivalent mRNA booster dose is recommended. The primary series dose and the additional dose are separated by at least 4 weeks. The booster dose is administered at least 2 months after the additional dose.

Safety considerations

Contraindications and precautions

Table A. Contraindications and precautions to Janssen COVID-19 vaccination

Contraindications and precautions to Janssen COVID-19 vaccination are summarized in Table A; see Contraindications and precautions to COVID-19 vaccination for additional information (e.g., people with a history of allergic reactions).

Medical condition or history	Guidance	Recommended action(s)
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)	Contraindication	Do not vaccinate with Janssen COVID-19 Vaccine. See Thrombosis with thrombocytopenia syndrome (TTS) section (below) for information on booster vaccination with a bivalent mRNA COVID-19 vaccine.
History of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as spontaneous or classic HIT	Not recommended	Do not vaccinate with Janssen COVID-19 Vaccine. These people should receive an mRNA or Novavax COVID-19 vaccine.
GBS within 6 weeks after receipt of Janssen COVID-19 Vaccine	Not recommended	Do not vaccinate with Janssen COVID-19 Vaccine. These people should receive a booster dose using a bivalent mRNA COVID-19 vaccine.
History of GBS	Precaution	See FAQs and GBS section (below) for additional information.

Abbreviations: TTS = thrombosis with thrombocytopenia syndrome; HIT = heparin-induced thrombocytopenia; GBS = Guillain-Barré syndrome

Post-vaccination symptoms

In clinical trials of Janssen COVID-19 Vaccine, pain at the injection site was the most frequently reported local reaction among vaccine recipients; erythema and swelling were reported less frequently. Fatigue and headache were the most commonly reported systemic reactions. Most systemic symptoms were mild to moderate in severity and resolved within 1–2 days. Overall, symptoms were more frequent in people ages 18–59 years compared to people ages 60 years and older.

Thrombosis with thrombocytopenia syndrome (TTS)

TTS is a rare syndrome that includes 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 Janssen COVID-19 Vaccine have been reported in males and females, with the highest risk in females ages 30–49 years.

All people who elect to receive 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 (i.e., Moderna or Pfizer-BioNTech) and Novavax COVID-19 vaccines instead of Janssen COVID-19 Vaccine. This guidance applies to both the 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 FDA-authorized or FDA-approved in the United States). These people are recommended to receive a bivalent mRNA booster dose at least 2 months following their dose of 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 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

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 (i.e., Moderna or Pfizer-BioNTech) or Novavax 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 people ages 40–64 years, with symptoms of GBS beginning within 42 days after Janssen COVID-19 vaccination; most GBS reports have been in males.

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 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. A bivalent mRNA COVID-19 vaccine should be used for any subsequent (i.e., booster) 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.

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Appendix B. People who received COVID-19 vaccine outside the United States

The recommendations for people vaccinated outside of the United States depend on the number and type of vaccine(s) received for the primary series and/or booster dose(s). 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. Age-appropriate Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccine products can be used. For additional guidance on primary and booster vaccination, see guidance for people who are **not** moderately or severely immunocompromised and guidance for people who are moderately or severely immunocompromised.

Table B. People who received COVID-19 vaccine outside the United States

Table B.1. Received a COVID-19 vaccine that is FDA-approved or FDA-authorized

Vaccination history	Recommended actions
Received all recommended primary dose(s)	• Do not repeat primary series. • Administer a bivalent mRNA booster dose if eligible.*†

Vaccination history	Recommended actions
Received a partial mRNA (i.e., Moderna or Pfizer-BioNTech) or Novavax COVID-19 vaccine primary series	• Do not restart primary series. • Complete primary series as close to the recommended time as possible with the same vaccine. • Administer a bivalent mRNA booster dose if eligible.*†
Received a monovalent booster dose(s) after completion of primary series	• Administer a bivalent mRNA booster dose if eligible.*
Received a bivalent mRNA booster dose after completion of the primary series	• Do not repeat if booster dose contained the original SARS-CoV-2 strain and Omicron BA.4/BA.5 variants • For other bivalent mRNA vaccines, see Special situation (after table footnotes).

Table B.2. Received a COVID-19 vaccine listed for emergency use by WHO but not approved or authorized by FDA‡

Vaccination history	Recommended actions
Received all recommended primary doses for that vaccine	• Do not repeat primary series. • Administer a bivalent mRNA booster dose if eligible.*†
Received partial primary series for that vaccine	• Complete the primary series with Moderna, Novavax, or Pfizer-BioNTech vaccine dose(s) as close to the recommended time as possible. Space from the last WHO-EUL vaccine dose by at least 28 days. • Administer a bivalent mRNA booster dose if eligible.*†
Received a monovalent booster dose after completion of primary series	• Administer a bivalent mRNA booster dose if eligible.*

Table B.3. Received a heterologous primary series or booster dose composed of doses of a COVID-19 vaccine listed for emergency use by WHO, at least one of which is not FDA-approved or FDA-authorized‡

Vaccination history	Recommended actions
Received a complete primary series	• Do not repeat primary series. • Administer a bivalent mRNA booster dose if eligible.*†
Received a monovalent booster dose after completion of primary series	• Administer a bivalent mRNA booster dose if eligible.*

Table B.4. 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
Received any number and combination of vaccine doses	• Do not count doses received toward vaccination in the US. • Start primary series at least 28 days after the last dose of vaccine. • Administer a bivalent mRNA booster dose if eligible.*†

*People ages 5 years and older who received a COVID-19 vaccine that is FDA-authorized, FDA-approved, or listed for emergency use by WHO should receive 1 bivalent mRNA booster dose.

†A monovalent Novavax booster dose (instead of a bivalent mRNA booster dose) may be used in limited situations in people ages 18 years and older who have not received any previous booster dose(s). The Novavax booster dose is administered at least 6 months after the last primary series dose.

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

Special situation: Do not administer a second bivalent mRNA booster dose if the person previously received a bivalent Moderna or Pfizer-BioNTech booster dose containing the original SARS-CoV-2 strain and Omicron BA.1 variant.

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

U.S. trial participants, along with non-U.S.-based participants in the same trial, who received all the recommended primary series doses of 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 up to date with their COVID-19 vaccines when they have received a bivalent mRNA booster dose. At this time, only the Medicago COVID-19 Vaccine in people ages 18 years and older meet these criteria.

Moderately or severely immunocompromised clinical trial participants should receive a third primary dose of an mRNA vaccine 28 days after receiving the second vaccine dose of a primary series as detailed in guidance for people who are moderately or severely immunocompromised, unless they have received or plan to receive a third primary dose through a clinical trial.

For information on booster doses, see guidance for people who are **not** moderately or severely immunocompromised and guidance for people who are moderately or severely immunocompromised.

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Appendix D. 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 product. Then continue with the recommended schedule of subsequent dose(s) unless otherwise noted (see footnotes to this Appendix).
    - For doses recommended to be repeated, some experts suggest delaying the repeat dose for 8 weeks after the invalid dose based on the potential for increased reactogenicity and the rare risk of myocarditis and pericarditis from an mRNA COVID-19 vaccine (i.e., Moderna or Pfizer-BioNTech) or Novavax COVID-19 Vaccine, particularly in groups at increased risk for myocarditis and pericarditis (e.g., males ages 12–39 years). 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. It is acceptable to administer the repeat dose at an interval earlier than 8 weeks if the interval is not sooner than the minimal interval noted in this table.

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 dose), unless otherwise stated.

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

Type	Administration error/deviation	Interim recommendation
Site/route	• Incorrect site (i.e., site other than the deltoid muscle or vastus lateralis muscle)	• Do not repeat dose.

Type	Administration error/deviation	Interim recommendation
	muscle)	
	• 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 younger than age 6 months)	• Do not give another dose at this time.*
Product and dosage	• Higher-than-authorized dose administered (e.g., incorrect dose volume, incorrect product resulting in higher-than-authorized dose)	• Do not repeat dose.†‡
	• Lower-than-authorized dose administered (e.g., leaked out of the syringe, equipment failure, recipient pulled away, incorrect product resulting in lower-than-authorized dose)	• Repeat dose immediately (no minimum interval).‡§ • However, if a half-volume dose of vaccine is administered to a patient recommended for the full volume, another half-volume dose can be administered on the same clinic day, and the 2 doses can count as 1 full dose.
	• Bivalent vaccine incorrectly administered for the primary series	• Bivalent Pfizer-BioNTech vaccine: Do not repeat dose. • Bivalent Moderna vaccine: Repeat 1 monovalent dose immediately (no minimum interval)§ because administration of the booster dose will result in a lower-than-authorized dose.
	• Monovalent vaccine incorrectly administered for a booster dose (if bivalent booster indicated)	• In general, do not repeat dose. • However, providers may administer 1 bivalent booster dose as a repeat dose based on clinical judgement and patient preference. In this case, space the repeat dose after the dose given in error by at least 2 months.
Storage and handling	• Dose administered after improper storage and handling (i.e., temperature excursion)	• Contact the manufacturer for information on the stability of the vaccine.¶ If the manufacturer does not have data to support the stability of the vaccine, repeat the dose immediately (no minimum interval).§
	• Dose administered past the expiration/beyond-use date	• Contact the manufacturer for information on the stability of the vaccine.¶ If the manufacturer does not have data to support the stability of the vaccine, repeat the dose immediately (no minimum interval).§
Intervals	• Any COVID-19 dose administered prior to the minimum interval#	• Repeat dose. Space repeat dose after the dose given in error by at least the minimum interval (Table 2 and Table 3).§
	• 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 vaccine 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 primary series	• Incorrect COVID-19 vaccine product inadvertently administered as part of a 2- or 3-dose primary series	• Do not repeat dose. • Any combination of Moderna, Novavax, or Pfizer-BioNTech vaccines is considered a complete primary series provided the indicated number of doses is administered. • If Janssen vaccine is administered, this counts as a single-dose series and no more primary doses are indicated. • Children ages 6 months–4 years who receive different mRNA products for the first 2 doses of an mRNA COVID-19 vaccine series should follow a 3-dose schedule. A third dose of either mRNA vaccine should be administered 8 weeks after the second dose to complete the 3-dose primary series. • Children ages 5–17 years who receive a mixed mRNA COVID-19 vaccine primary series can follow the Pfizer-BioNTech COVID-19 Vaccine schedule and receive a booster dose.
Diluent (Pfizer-BioNTech COVID-19 Vaccine formulation only [orange cap and maroon 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	• 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% sodium chloride)	• 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.†

Type	Administration error/deviation	Interim recommendation
	• 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. In addition to the minimum age, some experts suggest delaying the second dose for 8 weeks after the invalid dose based on the potential for increased reactogenicity and the rare risk of myocarditis and pericarditis from mRNA COVID-19 vaccine.

[†]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.

[‡]For FDA EUA dosing options for children who turn from age 4 years to 5 years (i.e., Pfizer-BioNTech), age 5 years to 6 years (i.e., Moderna), and age 11 years to 12 years (i.e., Moderna and Pfizer-BioNTech) during vaccination, see Transitioning from a younger to older age group. If the dosing is in accordance with the FDA EUA, it is not considered an error and VAERS reporting is not indicated.

[§]Some experts suggest delaying the repeat dose for 8 weeks after the invalid dose based on the potential for increased reactogenicity and the rare risk of myocarditis and pericarditis from mRNA (i.e., Moderna or Pfizer-BioNTech) and Novavax COVID-19 vaccines, particularly in groups at increased risk for myocarditis and pericarditis (e.g., males ages 12–39 years). Individual risk for COVID-19 and the likelihood for an adverse event following vaccination should be taken into consideration when recommending a longer interval. It is acceptable to administer the repeat dose at an interval earlier than 8 weeks if the interval is not sooner than the minimal interval noted in this table.

[¶]As of the date of this update, current manufacturer contact information is:

- Pfizer: 1-877-VAX-CO19 (1-877-829-2619)
- Moderna: 1-866-MODERNA (1-866-663-3762)
- Janssen: US Toll Free: 1-800-565-4008; US Toll: 1-908-455-9922
- Novavax: 1-844-NOVAVAX (1-844-668-2829)

Please see the package inserts and EUA provider factsheets for the most up-to-date manufacturer information.

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

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Appendix E. Triage of people with a history of allergies or allergic reactions

CONTRAINDICATION TO COVID-19 VACCINATION	PRECAUTION TO COVID-19 VACCINATION	NO CONTRAINDICATION OR PRECAUTION TO COVID-19 VACCINATION

CONTRAINDICATION TO COVID-19 VACCINATION	PRECAUTION TO COVID-19 VACCINATION	NO CONTRAINDICATION OR PRECAUTION TO COVID-19 VACCINATION
History of the following: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of a COVID-19 vaccine[1,2] • Known (diagnosed) allergy to a component of a COVID-19 vaccine[1]	**Among people without a contraindication, a history of:** • Anaphylaxis after non-COVID-19 vaccines or injectable therapies[3] • Non-severe, immediate (onset within 4 hours) allergic reaction[2] after a previous dose of COVID-19 vaccine[4] Note: People with an allergy-related contraindication to one type of COVID-19 vaccine have a precaution to the other types of COVID-19 vaccines.[4,5]	**Among people without a contraindication or precaution, a history of:** • Any allergy not listed as a contraindication or precaution
Actions: • Do not vaccinate • Consider referral to allergist-immunologist • Consider alternate vaccine type if age appropriate[1,5]	**Actions:** • Risk assessment[6] • Should consider a 30-minute observation period[4,5] • Consider referral to allergist-immunologist	**Actions:** • Proceed with vaccination • Should consider a 15-minute observation period per General Best Practice Guidelines

[1] COVID-19 vaccine-specific FDA fact sheets and U.S. COVID-19 Vaccine Product Information can be consulted for a full 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. However, some of these people may be able to receive Novavax or Janssen COVID-19 vaccine after a detailed risk assessment (see footnote 5 below).

[2] 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
- Any angioedema affecting the airway (i.e., tongue, uvula, or larynx)
- Diffuse rash which also involves mucosal surfaces (e.g., Stevens-Johnson Syndrome)

Non-severe allergic reactions may include:

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

[3] People with a history of anaphylaxis after 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.

[4] For people with a history of an immediate, non-severe allergic reaction after one type of COVID-19 vaccine, vaccination with a subsequent dose of that same type of COVID-19 vaccine should only be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Administering a different type of COVID-19 vaccine is another option; this can be done in the usual vaccination setting.

[5] Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Novavax and Janssen COVID-19 vaccines. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur.

- People with a known allergy to polysorbate have a contraindication to both Novavax and Janssen COVID-19 vaccines and a precaution to mRNA COVID-19 vaccines (i.e., Moderna or Pfizer-BioNTech).

- In all other cases, an allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the others.

For people with these precautions, referral to an allergist-immunologist should be considered. Healthcare professionals and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project. In patients with these precautions, vaccination should only be undertaken in an appropriate setting under the supervision of a healthcare professional experienced in the management of severe allergic reactions.

[6] 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 anaphylaxis after other vaccines or injectable therapies (Appendix E, footnote 3). 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 vaccine who are receiving another type that has been deemed a precaution 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. For information on the management of anaphylaxis see Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination and laboratory evaluation of people who experience anaphylaxis after vaccination.

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References and Previous Updates

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
- Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine: Updated Interim Recommendations from the Advisory Committee on Immunization Practices — United States, December 2021
- The Advisory Committee on Immunization Practices' Recommendation for Use of Moderna COVID-19 Vaccine in Adults Aged ≥18 Years and Considerations for Extended Intervals for Administration of Primary Series Doses of mRNA COVID-

19 Vaccines — United States, February 2022

- Interim Recommendations of the Advisory Committee on Immunization Practices for Use of Moderna and Pfizer-BioNTech COVID-19 Vaccines in Children Aged 6 Months–5 Years — United States, June 2022
- Interim Recommendation of the Advisory Committee on Immunization Practices for Use of the Novavax COVID-19 Vaccine in Persons Aged ≥18 years — United States, July 2022.
- Pfizer-BioNTech COVID-19 Vaccine Fact Sheet for Healthcare Providers (fda.gov)
- Moderna COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers (fda.gov)
- Novavax COVID-19 Vaccine, Adjuvanted | FDA
- Janssen COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers (fda.gov)
- Emergency Use Instructions for Healthcare Providers: Pfizer-BioNTech COVID-19 Vaccine for Primary, Additional, and/or Booster Doses (cdc.gov)
- Emergency Use Instructions for Healthcare Providers: Moderna COVID-19 Vaccine for Primary, Additional, and/or Booster Doses (cdc.gov)
- ACIP General Best Practice Guidelines for Immunization
- Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination

Previous Updates

October 12, 2022

- New COVID-19 booster recommendations for people ages 5 years and older to receive 1 bivalent mRNA booster after completion of a monovalent primary series or previously received monovalent booster dose(s); these recommendations replace all prior booster recommendations for this age group
  - Recommendations for use of a bivalent Moderna booster dose in people ages 6–17 years
  - Recommendations for use of a bivalent Pfizer-BioNTech booster dose in people ages 5–11 years

September 23, 2022

- Reorganization and consolidation of the Interim Clinical Considerations to enhance usability. COVID-19 vaccination schedules and guidance are unchanged.

September 2, 2022

- New booster recommendation for people ages 12 years and older to receive 1 bivalent mRNA booster after completion of a monovalent primary series; it replaces all prior booster recommendations for this age group
  - Recommendations for use of a bivalent Moderna booster dose in people ages 18 years and older
  - Recommendations for use of a bivalent Pfizer-BioNTech booster dose in people ages 12 years and older
- Updated guidance for observation periods following COVID-19 vaccination
- Updated guidance on COVID-19 vaccination and multisystem inflammatory syndrome (MIS) in children (MIS-C) and in adults (MIS-A)

August 22, 2022

- Guidance for primary series vaccination using Novavax COVID-19 Vaccine in adolescents ages 12–17 years
- Reorganization of Janssen COVID-19 Vaccine guidance into an appendix

August 11, 2022

- Updated guidance on COVID-19 vaccination following exposure to SARS-CoV-2

July 20, 2022

- Guidance for primary series vaccination using Novavax COVID-19 Vaccine in adults ages 18 years and older

- Guidance for primary series vaccination using Novavax COVID-19 Vaccine in adults ages 18 years and older
- Updated guidance on COVID-19 vaccination and myocarditis and pericarditis

June 30, 2022

- New clinical considerations for coadministration of mRNA COVID-19 vaccines and orthopoxvirus vaccines

June 24, 2022

- New guidance for use of Moderna COVID-19 Vaccine in children and adolescents ages 6–17 years

June 19, 2022

- New guidance for use of Pfizer-BioNTech COVID-19 Vaccine in children ages 6 months–4 years
- New guidance for use of Moderna COVID-19 Vaccine in children ages 6 months–5 years
- Reorganization of sections on COVID-19 vaccination recommendations and schedules
- Addition of new section in Special populations for infants and young children

May 20, 2022

- New guidance for use of a Pfizer-BioNTech COVID-19 Vaccine booster dose in children ages 5–11 years
- Updated guidance that the following people should receive a second COVID-19 booster dose:
  - People ages 12 years and older who are moderately or severely immunocompromised
  - People ages 50 years and older
- Updated guidance for people who are moderately or severely immunocompromised and are treated with B-cell-depleting therapies
- Clarification of COVID-19 vaccination guidance for multisystem inflammatory syndrome in children (MIS-C) and adults (MIS-A)
- Updated guidance for primary series vaccination after SARS-CoV-2 infection

April 21, 2022

- Added considerations for the option to receive a second COVID-19 vaccine booster dose
- Updated guidance for COVID-19 vaccination after SARS-CoV-2 infection

March 30, 2022

- Added guidance that people ages 12 years and older who are moderately or severely immunocompromised may choose to receive a second booster dose using an mRNA COVID-19 vaccine at least 4 months after the first booster dose
- Added guidance that adults ages 50 years and older who are not moderately or severely immunocompromised may choose to receive a second booster dose using an mRNA COVID-19 vaccine at least 4 months after the first booster dose
- Added guidance that people ages 18–49 years who are not moderately or severely immunocompromised and who received Janssen COVID-19 Vaccine as both their primary series dose and booster dose may receive a second booster dose using an mRNA COVID-19 vaccine at least 4 months after the first Janssen booster dose
- Further clarification of safety issues including those related to multisystem inflammatory syndrome in children (MIS-C) and adults (MIS-A) and myocarditis
- Updated information on the availability of Moderna COVID-19 Vaccine supplied in a vial with a red cap (0.25 mL dosage volume) and Moderna COVID-19 Vaccine supplied in a vial with a blue cap (0.5 mL dosage volume) for administration of a 50 µg booster dose.

February 22, 2022

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

February 11, 2022

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

January 6, 2022

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

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

- 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)

(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.

Last Reviewed: October 19, 2022