FORMULATIONS: 5 Years of Age and Older

Pfizer-BioNTech COVID-19 Vaccine

Vaccine Dosage Chart

The table below summarizes dosage information based on age, dose and medical indications for Pfizer-BioNTech COVID-19 Vaccine formulations. Use this table in conjunction with the FDA Fact Sheet for Healthcare Professionals and CDC clinical materials.

- Use the correct formulation for the age of the recipient. Formulations are NOT interchangeable. Check the vial label to ensure you are preparing and administering the correct formulation based on the age of the recipient.
  - 5 through 11 years of age: Orange cap and orange bordered label
  - 12 years of age and older: Purple cap and purple bordered label
- Vaccine must be mixed BEFORE administering. Use 0.9% preservative-free normal saline diluent supplied in the ancillary supplies kit. Diluent is not packaged with the vaccine.
- All Pfizer-BioNTech vaccines are administered by intramuscular (IM) injection. The injection site depends on recipient's age:
  - 5 through 11 years of age: Deltoid muscle (preferred)
  - 12 years of age and older: Deltoid muscle
  - Vastus lateralis muscle in the anterolateral thigh may be used.

PRIMARY SERIES DOSES

Primary Series (People 5 years of age and older)

If administering	Recipient's age	Use	Mix vaccine using	Administer
Primary series: Dose 1 or 2 (Separate by at least 21 days)	5 through 11 years of age	5 through 11 years of age formulation (orange cap) 	1.3 mL of diluent*	0.2 mL
	12 years of age and older	12 years of age and older formulation (purple cap) 	1. 8 mL of diluent*	0.3 mL

Additional Primary Dose for Moderately and Severely Immunocompromised Persons

If administering	Recipient's age	Use	Mix Vaccine Using	Administer
Any dose in the series (include the primary 2-dose series and an additional dose given at least 28 days after the primary series)	5 through 11 years of age	An additional dose for moderately and severely immunocompromised children in this age group has NOT been authorized by FDA or recommended by CDC.		
	12 years of age and older	12 years of age and older formulation (purple cap) 	1. 8 mL of diluent*	0.3 mL

BOOSTER DOSES

Booster Doses

If administering	Recipient's age	Use	Mix vaccine using	Administer
Booster dose (at least 6 months after completing the primary series†)	5 through 17 years of age	A booster dose in this age group has NOT been authorized by FDA or recommended by CDC.		
	18 years of age and older††	12 years of age and older formulation (purple cap) 	1.8 mL of diluent*	0.3 mL

*0.9% normal saline (preservative-free)

†including the additional primary series dose for moderately and severely immunocompromised persons.

††The Advisory Committee on Immunization Practices booster dose recommendations including eligible persons can be found at www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-covid19-vax-booster

FORMULATION: 5 Through 11 Years of Age

Pfizer-BioNTech COVID-19 Vaccine

Standing Orders for Administering Vaccine

Vaccine	Diluent	Dosage (amount)/ Route
Formulation: 5 through 11 years of age	1.3 mL of 0.9% sodium chloride (normal saline, preservative-free) diluent	0.2 mL/IM injection

Purpose

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

Procedure

Assess children 5 through 11 years of age for vaccination with Pfizer BioNTech COVID-19 Vaccine based on the following criteria:

- Primary-series vaccination
  - If the recipient has never received a COVID-19 vaccine, administer 1 dose of Pfizer-BioNTech COVID-19 vaccine.
  - If the recipient has received 1 previous dose of Pfizer-BioNTech COVID-19 Vaccine, administer the second dose at an interval of least 21 days.*
  - If 2 doses of an mRNA vaccine have been administered, the child is considered fully vaccinated. No additional doses are recommended.
- Children with a history of myocarditis or pericarditis:
  - If history is prior to COVID-19 vaccination may receive Pfizer-BioNTech formulation 5 thorough 11 years of age after the episode of myocarditis or pericarditis has completely resolved.
  - If myocarditis or pericarditis occurred after the first dose of an mRNA vaccine, experts advise no additional doses of any COVID-19 vaccine, including Pfizer-Bio-NTech formulation for children 5 through 11 years of age. Administration of the second dose of an mRNA COVID-19 vaccine series can be considered in certain circumstances after the episode of myocarditis or pericarditis has completely resolved. Considerations can be found at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-pfizer-biontech-moderna
  - Educational materials on myocarditis/pericarditis are available at http://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html, www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html
- Additional Clinical Considerations
  - For children who received a COVID-19 vaccine that is not currently authorized or approved in the United States, guidance can be found at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#not-authorized-vaccines
  - Pfizer-BioNTech COVID-19 vaccine may be coadministered with other vaccines without regard to timing, including simultaneous administration.
  - For recommendations for COVID-19 vaccination and SARS-CoV-2 infection, see https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#CoV-19-vaccination

Screen for contraindications and precautions

Contraindications:

History of:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine
- Known diagnosed allergy to a component of the vaccine (see https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Appendix-C for a list of vaccine components)

Precaution:

Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.

- Immediate allergic reaction¶ to any non-COVID-19 or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"])
  - This includes non-COVID-19 vaccines and therapies with multiple components and the component(s) that elicited the reaction is unknown
- Immediate (within 4 hours after vaccination) non-severe, allergic reaction to a previous dose of the COVID-19 vaccine
- Moderate to severe acute illness

*If the second dose is administered less than 17 days after the first dose (4-day grace period), the dose should be repeated. The repeat dose should be spaced at least 21 days after the improperly administered Pfizer-BioNTech dose.

¶An immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

- Provide all recipients and/or parents/legal guardians with a copy of the current Fact Sheet for Recipients and Caregivers.
- Prepare to administer the vaccine. Choose the correct formulation, injection site, needle gauge and length.
  - Prepare the vaccine following the manufacturer's directions using **1.3 mL** of 0.9% sodium chloride (normal saline, preservative-free) diluent
  - Use the 5 through 11 years of age formulation (multidose vial with orange cap and orange bordered label).
  - Deltoid muscle is preferred. Vastus lateralis muscle in the anterolateral thigh can also be used.
  - Needle gauge and length: Use a 22-25 gauge, 1 inch*
- Administer 0.2 mL of Pfizer-BioNTech COVID-19 vaccine formulation: 5 through 11 years of age age (orange cap and orange bordered label)
- Document vaccination.
  - COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (e.g., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration.
  - Document each recipient's vaccine administration information:
    - Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
    - Vaccination record card: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.
    - Immunization information system (IIS): Report the vaccination to the appropriate state/local IIS.
- Additional preparation and administration information is available on the manufacturer's website at www.cvdvaccine.com.
- Be prepared to manage medical emergencies.
  - Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:
    - **30 minutes;** Persons with a history of:
      - A contraindication to another type of COVID-19 vaccine product.
      - Immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine.
      - Immediate allergic reaction of any severity to a non-COVID-19 vaccine or injectable therapies
      - Anaphylaxis due to any cause.
    - **15 minutes:** All other persons
  - Syncope may occur in association with injectable vaccines, in particular among adolescents. Procedures should be in place to avoid falling injuries and manage syncopal reactions.
  - Have a written protocol to manage medical emergencies following vaccination, as well as equipment and medications, including at least 3 doses of epinephrine, H1 antihistamine, blood pressure monitor, and timing device to assess pulse.
  - Healthcare personnel who are trained and qualified to recognize the signs and symptoms of anaphylaxis as well as administer intramuscular epinephrine should be available at the vaccination location at all times.
  - For more information, please see:
    - **Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination at https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html**
    - **CDC's *General Best Practice Guidelines for Immunization*, "Preventing and Managing Adverse Reactions," at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html**
    - **Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting" at https://www.immunize.org/catg.d/p3082.pdf**
- Report adverse events to the Vaccine Adverse Event Reporting System (VAERS).
  - While this vaccine is under Emergency Use Authorization (EUA), healthcare professionals are required to report to VAERS:
    - Vaccine administration errors (whether associated with an adverse event [AE] or not)
    - Serious AEs (irrespective of attribution to vaccination)
    - Multisystem inflammatory syndrome (MIS) in adults or children
    - Cases of COVID-19 that result in hospitalization or death
    - Any additional AEs and revised safety requirements per the Food and Drug Administration's conditions for use of an authorized vaccine throughout the duration of the EUA
  - Healthcare professionals are encouraged to report to VAERS:
    - Clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event

*A 5/8 inch needle may be used if administering the vaccine in the deltoid muscle AND the skin is stretched tightly and the subcutaneous tissue is not bunched.

Pfizer-BioNTech COVID-19 Vaccine

Standing Orders for Administering Vaccine

Note: For more information/guidance, please contact the immunization program at your state or local health department or the appropriate state body (e.g., state board of medical/nursing/pharmacy practice).

Standing Orders Authorization

This policy and procedure shall remain in effect for all patients of the _____

effective_____ until rescinded or until _____ .

Medical director (or other authorized practitioner)

_____ / _____ /_____.

Adapted with appreciation from the Immunization Action Coalition (IAC) standing orders

FORMULATION: 5 Through 11 Years of Age

Pfizer-BioNTech COVID-19 Vaccine

Vaccine Preparation and Administration Summary

General Information

Vaccine: Pfizer-BioNTech: 5 through 11 years of age (orange cap and orange bordered label) **Use the correct formulation based on the age of the recipient**

Diluent: 1.3 mL of 0.9% sodium chloride (normal saline, preservative-free) Use a new vial every time.

Multidose vial: 10 doses per vial

Dosage: 0.2 mL

Prepare the vaccine using a NEW vial of diluent EVERY TIME. Discard the diluent vial and remaining diluent after mixing the vaccine.

Age Indications

5 through 11 years of age

Schedule for Primary Series and Boosters

- 2-dose series separated by 21 days*

Administration

Intramuscular (IM) injection in the deltoid muscle. The vastus lateralis muscle of the anterolateral thigh may be used.

Thawing Frozen Vaccine

- Vaccine stored at ultra-cold temperatures must be thawed before use.
- Thaw vaccine in the refrigerator or at room temperature:
  - Unpunctured vials may be stored in the refrigerator for up to 10 weeks.
  - Unpunctured vials maybe stored between 8°C to 25°C (46°F to 77°F) for a total of 12 hours prior to mixing (including thaw time).
- Amount of time needed to thaw vaccine varies based on temperature and number of vials.
- **Do NOT** refreeze thawed vaccine.
- Use CDC's beyond-use date labels to track storage time at refrigerated temperatures.

Prepare the Vaccine

Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.†

Remove vaccine from the storage unit. **Check the vial label to ensure it is the correct formulation based on the age of the recipient. The vial for children 5 through 11 years of age has an orange cap and orange border on the label.** Allow vaccine to come to room temperature. Vials can be held at room temperature at room temperature for up to 12 hours before mixing.

Before mixing, check the:
- Age indications on the label
- Expiration date of the vaccine and diluent
- Any beyond-use dates/times

NEVER use expired vaccine or diluent. **NEVER** use vaccine after the beyond-use date or times.

With the vaccine at room temperature, gently invert vial 10 times. **Do not shake the vial.** If the vial is shaken, contact the manufacturer. The vaccine is white to off-white in color and may contain opaque particles. Do not use if liquid is discolored.

Using a new, sterile alcohol prep pad for each vial, wipe off the stoppers of the diluent and vaccine vials. Using a 21-gauge (or narrower) needle, **withdraw 1.3 mL** of 0.9% sodium chloride (normal saline, preservative-free) into a mixing syringe. Discard diluent vial and any remaining diluent every time. **Do NOT** use bacteriostatic normal saline or other diluents to mix the vaccine.

Inject 1.3 mL 0.9% sodium chloride (normal saline, preservative-free) diluent into the vaccine vial.

Using the mixing syringe, remove 1.3 mL of air from the vaccine vial to equalize the pressure in the vaccine vial.

Gently invert the vial containing vaccine and diluent 10 times. The vaccine will be off-white in color. Do not use if discolored or contains particulate matter. **Do not shake.** If the vial is shaken, contact the manufacturer.

Note the date and time the vaccine was mixed on the vial.

Keep mixed vaccine between 2°C and 25°C (36°F to 77°F) for up to 12 hours. **Discard any unused vaccine after 12 hours.** Do not return to ultra-cold freezer storage.

* For more information, please see Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.

†Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between patients.

FORMULATION: 5 Through 11 Years of Age

Pfizer-BioNTech COVID-19 Vaccine

Vaccine Preparation and Administration Summary

Administer the Vaccine

Assess recipient status:

- Screen for contraindications and precautions.
- Review vaccination history.
- Review medical considerations.

Choose the correct vaccine formulation based on the age of the recipient and equipment, including the correct needle size.

- **Check the age indications on the label.** The vial for children 5 through 11 years of age has a orange cap and may have an orange border on the label. Do **NOT** administer vaccine that has a purple cap or purple bordered label on the vial to children younger than 12 years.
- Use a new, sterile needle and syringe for each injection. Use 1 mL low-dead volume syringes to withdraw the vaccine. If sufficient low-dead volume syringes are not available, withdraw vaccine using a combination of low dead-volume syringes and non-low dead-volume syringes.

Cleanse the stopper on the vial of mixed vaccine with a new, sterile alcohol prep pad. Withdraw 0.2 mL of mixed vaccine into the syringe.

- Regardless of the type of syringe used, ensure the amount of vaccine in the syringe equals 0.2 mL.
- If the amount of vaccine remaining in the vial cannot provide a full 0.2 mL dose, discard the vial and contents.
- **Do NOT** combine vaccine from multiple vials to obtain a dose.

Remove any significant air bubbles with the needle still in the vial to avoid loss of vaccine. Use the same needle* to withdraw and administer the vaccine. Ensure the prepared syringe is not cold to the touch. **Check the age indications on the vial label, again, to ensure it is the correct formulation based on the age of the recipient.**

Bring the dose of vaccine from the designated preparation area immediately to the patient treatment area for administration.

Ensure staff has the correct PPE before administering vaccines and implement policies for the use of face coverings for vaccine recipients older than 2 years of age (if tolerated).

Administer the vaccine immediately by intramuscular (IM) injection in the deltoid muscle. As an alternative, the vastus lateralis muscle may be used.

Observe recipients after vaccination for an immediate adverse reaction:

- **30 minutes:** Persons with a history of:
  - A contraindication to another type of COVID-19 vaccine product.
  - Immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine.
  - Immediate allergic reaction of any severity to a non-COVID-19 vaccine or injectable therapies
  - Anaphylaxis due to any cause.
- **15 minutes:** All other persons

*It is not necessary to change needles between drawing vaccine from a vial and injecting it into a recipient unless the needle has been damaged or contaminated.

Dose Scheduling for Primary Series

Vaccination History†	And	Then	Next Dose Due
0 doses	→	Give dose 1 today	Give dose 2 at least 21 days after dose 1§
1 dose (Pfizer-BioNTech COVID-19 Vaccine)	It has been at least 21 days since dose 1	Give dose 2 today	Series complete; no additional doses needed
	It has not been at least 21 days from dose 1	No dose today	Give dose 2 at least 21 days after dose 1§
2 doses (Pfizer-BioNTech COVID-19 Vaccine) at least 21 days apart§	→	→	Series complete; no additional doses needed

†COVID-19 vaccines may be coadministered with other vaccines, including simultaneous administration. When deciding whether to administer COVID-19 vaccines and other vaccines, providers should consider whether the person is behind or at risk of becoming behind on recommended vaccines. They should also consider the person's risk of vaccine-preventable diseases (e.g., during an outbreak) and the reactogenicity profile of the vaccines.

§Administer the 2nd dose as close as possible to the recommended interval of 21 days. It is not necessary to restart the series if the dose is given after the recommended interval.

Contraindications and Precautions

Contraindications:

History of:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine
- Known diagnosed allergy to a component of the vaccine (see https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Appendix-C for a list of vaccine components)

Precaution:

Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.

- Immediate allergic reaction¶ to any non-COVID-19 vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"])
  - This includes non-COVID-19 vaccines and therapies with multiple components and the component(s) that elicited the reaction is unknown
- Immediate (within 4 hours after vaccination) non-severe, allergic reaction to a previous dose of the COVID-19 vaccine
- Moderate to severe acute illness

For more information, please see Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States at www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.

¶An immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

Management of Anaphylaxis

Be prepared to manage medical emergencies.

- Have a written protocol to manage medical emergencies following vaccination, as well as equipment and medications, including at least 3 doses of epinephrine, H1 antihistamine, blood pressure monitor, and timing device to assess pulse.
- Healthcare personnel who are trained and qualified to recognize the signs and symptoms of anaphylaxis as well as administer intramuscular epinephrine should be available at the vaccination location at all times.

For more information, please see Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination at www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html.

Document the Vaccination

COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (i.e., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration.

Document each recipient's vaccine administration information in the:

- **Medical record:**
  - Vaccine and the date it was administered
  - Manufacturer and lot number
  - Vaccination site and route
  - Name and title of the person administering the vaccine
- **Personal vaccination record card (shot card):** Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.
- **Immunization information system (IIS) or "registry":** Report the vaccination to the appropriate state/local IIS.

Reporting Adverse Events

Healthcare professionals are required to report to the Vaccine Adverse Event Reporting System (VAERS):

- Vaccine administration errors (whether associated with an adverse event [AE] or not)
- Serious AEs (irrespective of attribution to vaccination)
- Multisystem inflammatory syndrome (MIS) in adults or children
- Cases of COVID-19 that result in hospitalization or death
- Any additional AEs and revised safety reporting requirements per the Food and Drug Administration's conditions for use of an authorized vaccine throughout the duration of the EUA

Adverse events should be reported even if the cause is uncertain. Healthcare professionals are also encouraged to report any clinically significant AEs that occur after vaccine administration. Submit reports to www.vaers.hhs.gov.

For additional information, see the vaccine manufacturer's product information at www.cvdvaccine.com.

For additional information on preventing, reporting, and managing mRNA COVID-19 vaccine administration errors, see https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-A

*For the purpose of this guidance, an immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

†Consider consultation with an allergist-immunologist to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax Project https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html. Vaccination of these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

- People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy) have a precaution to Janssen COVID-19 vaccination. People who have previously received an mRNA COVID-19 Vaccine dose should wait at least 28 days to receive Janssen COVID-19 Vaccine.
- People with a contraindication to Janssen COVID-19 vaccine (including due to a known polysorbate allergy) have a precaution to mRNA COVID-19 vaccination.

FORMULATION: 5 Through 11 Years of Age

Pfizer-BioNTech COVID-19 Vaccine

Storage and Handling Summary

Basics

- Store vaccine in an ultra-cold freezer or refrigerator. See guidance below for each storage unit.
- Do **NOT** store in:
  - The thermal shipping container*
  - A freezer
- Check and record storage unit temperatures each workday. See guidance below for each type of storage unit. Save storage records for 3 years, unless your jurisdiction requires a longer time period.

Deliveries

Vaccine

1. The vaccine will arrive in a thermal shipping container at ultra-cold temperatures between -90°C and -60°C (-130°F and -76°F) with dry ice or between -25°C and -15°C (-13°F and 5°F). The vial for children 5 through 11 years of age has an orange cap and orange border on the label.
2. Follow the manufacturer's guidance for unpacking the vaccine. (www.cvdvaccine-us.com/product-storage-and-dry-ice).
3. Remove the temperature monitoring device from the shipping container and return using the included pre-labeled foldable return box.
4. Dispose of the single-use thermal shipping container. Do NOT use the thermal shipping container for storage.*

Ancillary Supply Kit

An ancillary supply kit will be delivered separately from the vaccine and includes:

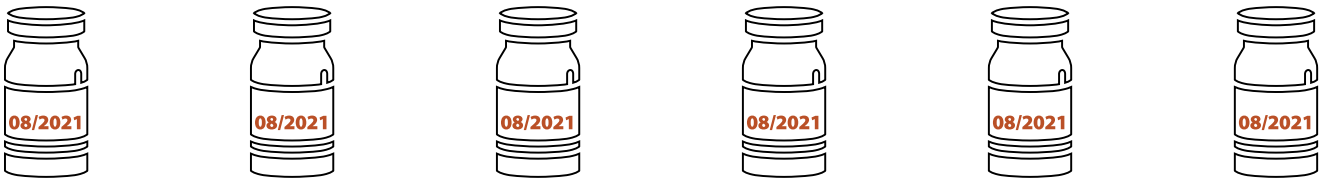
- **Mixing supplies:** Diluent, needles, syringes, and sterile alcohol prep pads
  - Mixing supplies are packaged separately with a green identification label.
  - Do NOT use mixing supplies to administer vaccine.
- **Administration supplies:** Needles, syringes, sterile alcohol prep pads, vaccination record cards, and some PPE.
  - Ancillary supply kits have been reconfigured to support the number of doses ordered.

*Thermal shipping containers delivered to Alaska, Hawaii, and the US-affiliated Pacific Islands may be used as temporary storage. Refer to the manufacturer for more detailed guidance on using the thermal shipping container for storage: https://www.cvdvaccine-us.com/product-storage-and-dry-ice

Ultra-Cold Freezer

Before mixing, the vaccine may be stored in an ultra-cold freezer between -90°C and -60°C (-130°F and -76°F).

- Store vaccine vials upright in the tray or box.
- Protect from light.
- Vaccine may be stored until the expiration date. Vaccine expires 6 months after the manufacture date.
  - The manufacture date is printed on the vial (orange cap)
  - Count out 6 months, using the month printed on the vial as month 1.
  - The vaccine expires on the last day of the 6th month
  - Expired vaccine should NEVER be administered. To prevent this, use CDC's COVID-19 Vaccine Expiration Date Tracking Tool
  - As the expiration date approaches, contact the manufacturer to determine if it has been extended. Do not discard vaccine without ensuring the expiration date has passed.



Month 1: August 2021 **(Printed on vial)**

Month 2: September 2021

Month 3: October 2021

Month 4: November 2021

Month 5: December 2021

Month 6: January 2022

Expires January 31, 2022

FORMULATION: 5 Through 11 Years of Age

Pfizer-BioNTech COVID-19 Vaccine

Storage and Handling Summary

Refrigerator

Before mixing, the vaccine may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 10 weeks. After 10 weeks, contact the manufacturer for guidance. If directed to discard any remaining vials, follow the manufacturer's and your jurisdiction's guidance for proper disposal.

- Monitor how long the vaccine has been in the refrigerator using CDC's beyond-use date labels for Pfizer-BioNTech COVID-19 Vaccine.
- Store the vaccine in the tray or box.
- Protect from light.
- Do NOT refreeze thawed vaccine.

Temperature Monitoring

Ultra-cold freezer or refrigerator: Storage unit temperatures must be monitored regularly, checked, and recorded at the beginning of the workday to determine if any temperature excursions have occurred since the last temperature check. For accurate temperature monitoring, use a digital data logger (DDL) with a detachable probe that best reflects vaccine temperatures.

- Ultra-cold temperatures: Use a probe designed specifically to measure ultra-cold temperatures.
- Refrigerated storage: Use a probe buffered with glycol, glass beads, sand, or Teflon®.

Check and record the temperature daily using CDC's temperature log. Use one of the options below:

- **Option 1 (preferred): Minimum/Maximum (Min/Max) Temperature**
  Most DDLs display min/max temperatures. Check and record the min/max temperatures at the start of each workday.
- **Option 2: Current Temperature**
  If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday. Review the continuous DDL temperature data daily.

Diluent

0.9% sodium chloride (normal saline, preservative-free) diluent is included in the ancillary supply kits. Follow the manufacturer's guidance for storing the diluent.

Mixed Vaccine

- Once mixed, vials can be stored between 2°C to 25°C (35°F to 77°F) for up to 12 hours.
- Discard any remaining vaccine after 12 hours.
- Mixed vaccine should NOT be returned to ultra-cold freezer storage.

Disposal

Once vaccine has reached its expiration or beyond-use date, contact the manufacturer for guidance on whether it can still be used. If instructed to dispose of vaccine, dispose of the vial (with any remaining vaccine) and packaging as medical waste according to your local and state regulations. Contact your jurisdiction's immunization program (https://www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html) for guidance.

CDC's Pfizer-BioNTech COVID-19 Vaccine materials https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html

CDC's *Vaccine Storage and Handling Toolkit* https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

CDC's Pfizer Beyond-Use Date (BUD) labels https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/bud-tracking-labels.pdf

CDC's Freezer and Refrigerator Temperature Logs https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html

For additional information, refer to the manufacturer's website at www.cvdvaccine.com

Pfizer-BioNTECH COVID-19 Vaccine Storage and Handling Label • FORMULATION: 5 Through 11 Years of Age - *Intended for print only*

FORMULATION: 5 Through 11 Years of Age

Pfizer-BioNTech COVID-19 Vaccine

Ages: 5 through 11 years of age

Use for: Any dose in the 2-dose series.
COVID-19 vaccines are NOT interchangeable.
Both doses should be COVID-19 vaccine (Pfizer).

Route: Intramuscular (IM) injection

Prior to administration, mix with 0.9% sodium chloride (normal saline, preservative-free) diluent ONLY.

Beyond Use Date/Time:

DO NOT PUT IN FREEZER

Refrigerator: Between 2°C and 8°C (36°F and 46°F) for up to 10 weeks.

Mixed vaccine: Use within 12 hours of mixing.

FORMULATION: 5 Through 11 Years of Age

Pfizer-BioNTech COVID-19 Vaccine

Ages: 5 through 11 years of age

Use for: Any dose in the 2-dose series.
COVID-19 vaccines are NOT interchangeable.
Both doses should be COVID-19 vaccine (Pfizer).

Route: Intramuscular (IM) injection

Prior to administration, mix with 0.9% sodium chloride (normal saline, preservative-free) diluent ONLY.

Beyond Use Date/Time:

DO NOT PUT IN FREEZER

Refrigerator: Between 2°C and 8°C (36°F and 46°F) for up to 10 weeks.

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COVID-19 vaccines are NOT interchangeable.
Both doses should be COVID-19 vaccine (Pfizer).

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Refrigerator: Between 2°C and 8°C (36°F and 46°F) for up to 10 weeks.

Mixed vaccine: Use within 12 hours of mixing.

FORMULATION: 5 Through 11 Years of Age

Pfizer-BioNTech COVID-19 Vaccine

Ages: 5 through 11 years of age

Use for: Any dose in the 2-dose series.
COVID-19 vaccines are NOT interchangeable.
Both doses should be COVID-19 vaccine (Pfizer).

Route: Intramuscular (IM) injection

Prior to administration, mix with 0.9% sodium chloride (normal saline, preservative-free) diluent ONLY.

Beyond Use Date/Time:

DO NOT PUT IN FREEZER

Refrigerator: Between 2°C and 8°C (36°F and 46°F) for up to 10 weeks.

Mixed vaccine: Use within 12 hours of mixing.

FORMULATION: 5 Through 11 Years of Age

Pfizer-BioNTech COVID-19 Vaccine

Transporting Vaccine for Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations

Procedure

Follow storage and handling best practices outlined in CDC's *Vaccine Storage and Handling Toolkit,* COVID-19 Vaccine Addendum (https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf), to maintain the cold chain when packing and transporting vaccine.

Transport Pfizer-BioNTech COVID-19 Vaccine with a temperature monitoring device in a:

- Portable ultra-cold freezer unit
- Portable refrigerator unit
- Container/packout qualified to maintain the recommended temperatures

Upon arrival at the clinic, place vaccine in an on-site storage unit that maintains recommended temperatures, if available. If there is no storage unit available, keep the vaccine in the transport container, maintaining recommended temperatures.

Best Practices for Transporting mRNA Vaccines

- Protect vaccines as much as possible from drops, shocks, and vibration.
- To minimize movement, transport vials in the carton whenever possible.
- If individual, undiluted vials must be transported:
  - Place vials with padding materials like bubble wrap or similar materials to prevent breaking.
  - Secure storage containers during transport.
  - Keep vaccine vials upright whenever possible.
  - Protect from light.

Temperature monitoring:

Record time and minimum/maximum temperatures:

- At the start of transport
- Whenever the transport container is opened
- When transport concludes

General Information

- Transport equal amounts of vaccines, diluents, and ancillary supplies (including vaccination record cards and personal protective equipment).
- **ONLY** unpunctured vials may be transported.
  - Unpunctured vaccine vials may be transported more than once.
- Transport thawed vaccine at refrigerated temperatures.
  - Individual vials or partially filled trays must be transported at refrigerated temperatures.
  - Vaccine stored at refrigerated temperatures should not be refrozen.
- Do **NOT** transport punctured vials or pre-drawn syringes

Temperatures and Transport Container	Temperature Monitoring Device	Beyond-Use Time/Date	Additional Considerations
Ultra-cold transport: Between -90°C and -60°C (-130°F and -76°F) in a portable ultra-cold freezer or qualified container/ packout	Digital data logger (DDL) with a probe designed to measure ultra-cold temperatures	Vaccine may be stored in an ultra-cold freezer until the expiration date.	Only full trays of vaccine may be transported at ultra-cold temperatures.
Refrigerated transport: Between 2°C and 8°C (36°F and 46°F) in a portable refrigerator or qualified container/packout	DDL with a buffered temperature probe that displays current, minimum, and maximum temperatures	**Unpunctured vials only:** Vaccine may be stored at refrigerated temperatures for up to 10 weeks. Vials may be transported more than once.	Any time used for transport counts against the 10 week time limit for storage at these temperatures. Punctured, mixed vials or predrawn syringes **CANNOT** be transported.

Resources:

CDC's Transport Temperature Log
https://www.cdc.gov/vaccines/covid-19/downloads/transport-temperature-log.pdf

CDC's Beyond-Use Date (BUD) labels
https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/bud-tracking-labels.pdf

USP COVID-19 Vaccine Toolkit: Operational Considerations for Healthcare Practitioners
https://www.usp.org/covid-19/vaccine-handling-toolkit

Prevaccination Checklist for COVID-19 Vaccines

For vaccine recipients:

The following questions will help us determine if there is any reason you should not get the COVID-19 vaccine today. **If you answer "yes" to any question, it does not necessarily mean you should not be vaccinated.** It just means additional questions may be asked. If a question is not clear, please ask your healthcare provider to explain it.

Name _____

Age _____

	Yes	No	Don't know
1. Are you feeling sick today?	☐	☐	☐
2. Have you ever received a dose of COVID-19 vaccine?	☐	☐	☐
• If yes, which vaccine product did you receive? ☐ Pfizer-BioNTech ☐ Moderna ☐ Janssen *(Johnson & Johnson)* ☐ Another Product _____			
• Have you received a complete COVID-19 vaccine series *(i.e., 1 dose Janssen or 2 doses of an mRNA vaccine [Pfizer-BioNTech, Moderna])*?	☐	☐	
• Did you bring your vaccination record card or other documentation?	☐	☐	
3. Have you ever had an allergic reaction to: *(This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that caused you to go to the hospital. It would also include an allergic reaction that caused hives, swelling, or respiratory distress, including wheezing.)*			
• A component of a COVID-19 vaccine, including either of the following: ○ Polyethylene glycol *(PEG)*, which is found in some medications, such as laxatives and preparations for colonoscopy procedures	☐	☐	☐
○ Polysorbate, which is found in some vaccines, film coated tablets, and intravenous steroids	☐	☐	☐
• A previous dose of COVID-19 vaccine	☐	☐	☐
4. Have you ever had an allergic reaction to another vaccine *(other than COVID-19 vaccine)* or an injectable medication? *(This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that caused you to go to the hospital. It would also include an allergic reaction that caused hives, swelling, or respiratory distress, including wheezing.)*	☐	☐	☐

5. Check all that apply to you:

- ☐ Am a female between ages 18 and 49 years old
- ☐ Am a male between ages 12 and 29 years old
- ☐ Have a history of myocarditis or pericarditis
- ☐ Had a severe allergic reaction to something other than a vaccine or injectable therapy such as food, pet, venom, environmental or oral medication allergies
- ☐ Had COVID-19 and was treated with monoclonal antibodies or convalescent serum
- ☐ Diagnosed with Multisystem Inflammatory Syndrome (MIS-C or MIS-A) after a COVID-19 infection
- ☐ Have a bleeding disorder
- ☐ Take a blood thinner
- ☐ Have a weakened immune system (i.e., HIV infection, cancer) or take immunosuppressive drugs or therapies
- ☐ Have a history of heparin-induced thrombocytopenia (HIT)
- ☐ Am currently pregnant or breastfeeding
- ☐ Have received dermal fillers
- ☐ History of Guillain-Barré Syndrome (GBS)

Form reviewed by _____ **Date** _____

Adapted with appreciation from the Immunization Action Coalition (IAC) screening checklists

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Prevaccination Checklist for COVID-19 Vaccines

Information for Healthcare Professionals

For additional information on COVID-19 vaccine clinical guidance, see https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.

For additional information on Advisory Committee on Immunization Practices *General Best Practice Guidelines for Immunization*, see https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html.

COVID-19 vaccines are authorized for different age groups and are given intramuscularly as a two-dose series* or single dose.

VACCINE PRODUCT	AUTHORIZED AGE GROUPS	SERIES	INTERVAL
Pfizer-BioNTech COVID-19 Vaccine	12 years of age and older	2 doses*	21 days
Moderna COVID-19 Vaccine	18 years of age and older	2 doses*	28 days
Janssen COVID-19 Vaccine (Johnson & Johnson)	18 years of age and older	1 dose	N/A

Anyone outside the authorized age groups for a product should not receive the vaccine.

Postvaccination Observation Times for People without Contraindications to COVID-19 Vaccination

- **30 minutes:**
  - History of an immediate allergic reaction of any severity to a vaccine or injectable therapy
  - Contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to mRNA vaccines who receive a Janssen (Johnson & Johnson COVID-19 Vaccine)
  - History of anaphylaxis due to any cause
- **15 minutes:**
  - All other people

Co-administration of COVID-19 vaccines and other vaccines

COVID-19 vaccines and other vaccines **may be administered without regard to timing.** This includes simultaneous administration of COVID-19 vaccines and other vaccines during the same visit. Other vaccines can also be administered anytime before or after COVID-19 vaccination.

1. Are you feeling sick today?

While there is no evidence acute illness reduces vaccine efficacy or increases adverse reactions, as a precaution, **delay vaccinating patients with moderate or severe illness** until the illness has improved.

Defer vaccination of people with current SARS-CoV-2 infection until the person has recovered from acute illness and discontinued isolation. This recommendation applies regardless of whether the SARS-CoV-2 infection occurred before the recipient received an initial dose or between doses, for a two-dose vaccine. Viral or serological testing to assess for current or prior infection solely for the purpose of vaccine-decision making is not recommended.

People with mild illnesses can be vaccinated. Do not withhold vaccination if a person is taking antibiotics.

*People with moderate to severe immune compromise can receive an additional dose after an initial 2-dose primary mRNA COVID-19 vaccine series. See clinical considerations on page 9 for more information.

2. Have you ever received a dose of COVID-19 vaccine?

COVID-19 vaccines are not interchangeable.

For two-dose products, check medical records, immunization information systems, and vaccination record cards to help determine the initial product received. If the vaccine product for the first dose cannot be determined or is no longer available, any available mRNA vaccine may be administered (separate doses by at least 28 days). If two doses of different mRNA COVID-19 vaccine are inadvertently administered, no additional doses of either product are recommended.

People who received a trial vaccine should consult with the trial sponsors to determine if it is possible to receive additional doses.

For people who received a COVID-19 vaccine outside the United States:

- People who received all recommended doses of an FDA-authorized COVID-19 vaccine do not need any additional doses. People who received the first dose of an FDA-authorized COVID-19 vaccine that requires two doses **do not need** to restart the vaccine series in the United States but should receive the second dose as close to the recommended time as possible.
- People who have received all recommended doses of a COVID-19 vaccine listed for emergency use by WHO **do not need** any additional doses with an FDA-authorized COVID-19 vaccine. See Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States (https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html) for a list of WHO vaccines for emergency use.
- People who have not received all the recommended doses of a COVID-19 vaccine listed for emergency use by WHO may be offered a complete FDA-authorized COVID-19 vaccine series. Wait at least 28 days after the last dose of the non-FDA-authorized vaccine before administering an FDA-authorized COVID-19 vaccine.
- People who received all or some of the recommended doses of a COVID-19 vaccine not listed for emergency use by WHO and not authorized by FDA may be offered a complete FDA-authorized COVID-19 vaccine series. Wait at least 28 days after the last dose of the non-authorized vaccine before administering an FDA-authorized COVID-19 vaccine.

3. Have you ever had an allergic reaction to:

- A component of a COVID-19 vaccine, including:
  - Polyethylene glycol (PEG), which is found in some medications, such as laxatives and preparations for colonoscopy procedures
  - Polysorbate, which is found in some vaccines, film-coated tablets, and intravenous steroids
- A previous dose of COVID-19 vaccine

People with an immediate allergic reaction* to a previous COVID-19 vaccine dose or a known (diagnosed) allergy to a component of the vaccine have a contraindication to vaccination.

People with a contraindication to an mRNA COVID-19 vaccine should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna). People with a contraindication to mRNA COVID-19 vaccines (including due to a known [diagnosed] allergy to PEG†) have a precaution to Janssen COVID-19 Vaccine.

People with a contraindication to Janssen COVID-19 Vaccine (including due to a known [diagnosed] allergy to polysorbate*) have a precaution to mRNA COVID-19 vaccines.

People with a history of immediate allergic reaction to a vaccine or injectable therapy that contains multiple components, one or more of which is a component of a COVID-19 vaccine, have a precaution to vaccination with that COVID-19 vaccine, even if it is unknown which component elicited the allergic reaction.

*When vaccine recipients report a history of an immediate allergic reaction, providers should attempt to determine whether reactions reported following vaccination are consistent with immediate allergic reactions versus other types of reactions commonly observed following vaccination, such as vasovagal reaction or postvaccination side effects (which are not contraindications to receiving the second of an mRNA COVID-19 vaccine dose).

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

Prevaccination Checklist for COVID-19 Vaccines

Information for Healthcare Professionals

COVID-19 Vaccine Components*

Description	Pfizer-BioNTech mRNA COVID-19 Vaccine	Moderna mRNA COVID-19 Vaccine	Janssen COVID-19 Vaccine
Active ingredients	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Viral Vector; 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	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	2-hydroxypropyl-β-cyclodextrin (HBCD)
	Cholesterol	Cholesterol	Citric acid monohydrate
	(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
	Sodium chloride	Tromethamine	Sodium chloride
	Monobasic potassium phosphate	Tromethamine hydrochloride	Ethanol
	Potassium chloride	Acetic acid	
	Dibasic sodium phosphate dihydrate	Sodium acetate	
	Sucrose	Sucrose	

*None of the vaccines contain eggs, gelatin, latex, or preservatives.

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

In patients who experience post-vaccination symptoms, determining the etiology (including allergic reaction, vasovagal reaction, or vaccine side effects) is important to determine whether a person can receive additional doses of the vaccine (including the 2nd dose of an mRNA COVID-19 vaccine). The following table of signs and symptoms is meant to serve as a resource but may not be exhaustive, and patients may not have all signs or symptoms. Providers should use their clinical judgement when assessing patients to determine the diagnosis and appropriate management.

Characteristic	Immediate allergic reactions (including anaphylaxis)	Vasovagal reactions	Vaccine side effects (local and systemic)
Timing after vaccination	Most occur within 15-30 minutes of vaccination	Most occur within 15 minutes	Median of 1 to 3 days after vaccination (with most occurring the day after vaccination)
SIGNS AND SYMPTOMS			
Characteristic	**Immediate allergic reactions (including anaphylaxis)**	**Vasovagal reactions**	**Vaccine side effects (local and systemic)**
Constitutional	Feeling of impending doom	Feeling warm or cold	Fever, chills, fatigue
Cutaneous	Skin symptoms present in ~90% of people with anaphylaxis, including pruritus, urticaria, flushing, angioedema	Pallor, diaphoresis, clammy skin, sensation of facial warmth	Pain, erythema or swelling at injection site, lymphadenopathy in same arm as vaccination
Neurologic	Confusion, disorientation, dizziness, lightheadedness, weakness, loss of consciousness	Dizziness, lightheadedness, syncope (often after prodromal symptoms for a few seconds or minutes), weakness, changes in vision (such as spots of flickering lights, tunnel vision), changes in hearing	Headache

Characteristic	Immediate allergic reactions (including anaphylaxis)	Vasovagal reactions	Vaccine side effects (local and systemic)
Respiratory	Shortness of breath, wheezing, bronchospasm, stridor, hypoxia	Variable; if accompanied by anxiety, may have an elevated respiratory rate	N/A
Cardiovascular	Hypotension, tachycardia	Variable; may have hypotension or bradycardia during syncopal event	N/A
Gastrointestinal	Nausea, vomiting, abdominal cramps, diarrhea	Nausea, vomiting	Vomiting or diarrhea may occur
Musculoskeletal	N/A	N/A	Myalgia, arthralgia

VACCINE RECOMMENDATIONS

Characteristic	Immediate allergic reactions (including anaphylaxis)	Vasovagal reactions	Vaccine side effects (local and systemic)
If vaccinated with mRNA COVID-19 vaccine as first dose, recommended to receive second mRNA vaccine dose?	No	Yes	Yes

Healthcare providers or health departments in the United States can request a consultation from the Clinical Immunization Safety Assessment COVIDvax project (https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html) for a complex COVID-19 vaccine safety question not readily addressed by CDC guidance about an individual patient residing in the United States.

Healthcare professionals should be familiar with identifying immediate-type allergic reactions, including anaphylaxis, and be competent in treating these events at the time of vaccine administration. Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of a COVID-19 vaccine. See Management of Anaphylaxis at COVID-19 Vaccination Sites | CDC for additional guidance. https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html

Syncope may occur in association with injectable vaccines, in particular among adolescents. Procedures should be in place to avoid falling injuries and manage syncopal reactions. All people are recommended to be observed following COVID-19 vaccination for at least 15 minutes. Patients should be seated or lying down during the observation period to decrease the risk for injury should they faint. If syncope develops, patients should be observed until symptoms resolve.

4. Have you ever had an allergic reaction to another vaccine (other than COVID-19 vaccine) or another injectable medication?

A history of any immediate allergic reaction (within 4 hours) to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of COVID-19 vaccines) is a precaution to currently authorized COVID-19 vaccines. Vaccine may be given, but counsel patients about unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination. Deferral of vaccination and/or consultation with an allergist-immunologist should be considered. Considerations for vaccination include risk of exposure to SARS-CoV-2, risk of severe disease or death due to COVID-19, previous infection with COVID-19, unknown risk of anaphylaxis following COVID-19 vaccination, and ability of recipient to receive care immediately for anaphylaxis, if necessary. **These individuals should be observed for 30 minutes after vaccination.**

5. Clinical Considerations:

Response	Consideration
Female between 18 and 49 years of age	Women 18 through 49 years of age can receive any FDA-authorized COVID-19 vaccine. However, they should be informed of the rare but increased risk of thrombosis with thrombocytopenia syndrome (TTS) after receipt of the Janssen COVID-19 Vaccine www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine and the availability of other FDA- authorized COVID-19 vaccines. 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. Additional recipient education materials can be found at www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html.
Male between 12 and 29 years of age	Males 12 through 29 years of age can receive any FDA-authorized vaccine. However, people receiving an mRNA COVID-19 vaccine, especially males in this age group and their parents/legal representative (when relevant), should be informed of the risk of developing myocarditis (an inflammation of the heart muscle) or pericarditis (inflammation of the lining around the heart) after receipt of an mRNA vaccine. Cases of myocarditis or pericarditis have occurred predominantly in males aged 12–29 years within a few days after receiving the second dose of an mRNA COVID-19 vaccine. The risk of developing either myocarditis or pericarditis is low. Additional recipient education materials can be found at www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html.
History of myocarditis or pericarditis	***Myocarditis or pericarditis after receipt of the first dose of an mRNA COVID-19 vaccine series but before administration of the second dose*** Experts recommend that people who develop myocarditis or pericarditis after a first dose of an mRNA COVID-19 vaccine defer receiving the second dose, until additional safety data are available. Administration of the second dose of an mRNA COVID-19 vaccine series can be considered in certain circumstances after the episode of myocarditis or pericarditis has completely resolved. Decisions about proceeding with the second dose should include a conversation between the patient, their parent/legal representative (when relevant), and their clinical team, which may include a cardiologist. Considerations for vaccination can be found at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#underlying-conditions. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment Project at www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html. ***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 may receive any FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved.
Had a severe allergic reaction to something other than a vaccine or injectable therapy such as food, pet, venom, environmental or oral medication allergies	Allergic reactions, including severe allergic reactions, **NOT** related to vaccines, injectable therapies, or components of COVID-19 vaccines, are **NOT** contraindications or precautions to vaccination with currently authorized COVID-19 vaccines. However, individuals who have had severe allergic reactions to anything, regardless of cause, **should be observed for 30 minutes after vaccination.**

Response	Consideration
Had COVID-19 and was treated with monoclonal antibodies or convalescent serum	Vaccination should be offered to people regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection. There is no recommended minimal interval between infection and vaccination. However, vaccination should be deferred for at least 90 days if a patient received monoclonal antibodies or convalescent serum as treatment for COVID-19. This is a precautionary measure until additional information becomes available, to avoid interference of the antibody treatment with vaccine-induced immune responses.
Had multisystem inflammatory syndrome; either MIS-C (children) or MIS-A (adults)	It is unknown if people with a history of MIS-C or MIS-A are at risk for a dysregulated immune response to COVID-19 vaccination. People with a history of MIS-C or MIS-A may choose to be vaccinated. Considerations for vaccination may include: ■ Clinical recovery from MIS-C or MIS-A, including return to normal cardiac function ■ Personal risk of severe acute COVID-19 (e.g., age, underlying conditions) ■ Level of COVID-19 community transmission and personal risk of reinfection ■ Lack of safety data of COVID-19 vaccines following these illnesses ■ Timing of any immunomodulatory therapies (general best practice guidelines for immunization can be consulted for more information https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html) Because current evidence suggests that the risk of SARS-CoV-2 reinfection is low in the months after initial infection, people with a history of MIS-C or MIS-A should consider delaying vaccination until they have recovered from their infection and for 90 days after the date of diagnosis of MIS-C or MIS-A. A conversation between the patient, their guardian(s), and their clinical team or a specialist may assist with COVID-19 vaccination decisions. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment Project at www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html.
Have a bleeding disorder **Take a blood thinner**	As with all vaccines, any COVID-19 vaccine product may be given to these patients, if a physician familiar with the patient's bleeding risk determines that the vaccine can be administered intramuscularly with reasonable safety. ACIP recommends the following technique for intramuscular vaccination in patients with bleeding disorders or taking blood thinners: A fine-gauge needle (23-gauge or smaller caliber) should be used for the vaccination, followed by firm pressure on the site, without rubbing, for at least 2 minutes. People who regularly take aspirin or anticoagulants as part of their routine medications do not need to stop these medications prior to receipt of any COVID-19 vaccine.

Response	Consideration
Have a weakened immune system (HIV infection, cancer) **Take immunosuppressive drugs or therapies**	COVID-19 vaccines may be administered to people with underlying medical conditions, such as HIV infection or other immunocompromising conditions, or who take immunosuppressive medications or therapies, who have no contraindications to vaccination. Consider an additional dose of an mRNA COVID-19 vaccine after an initial 2-dose primary mRNA COVID-19 vaccine series for people with moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments. These conditions and treatments include but are not limited to: ■ Active treatment for solid tumor and hematologic malignancies ■ Receipt of solid-organ transplant and taking immunosuppressive therapy ■ Receipt of CAR-T-cell or hematopoietic stem cell transplant (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 ■ Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (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. Whenever possible, administer the same additional mRNA COVID-19 vaccine product as the initial 2-dose mRNA COVID-19 primary vaccine series (Pfizer-BioNTech or Moderna). If the mRNA COVID-19 vaccine product given for the first two doses is not available, the other mRNA COVID-19 vaccine product may be administered. A person should not receive more than three valid mRNA COVID-19 vaccine doses. Until additional data are available, the additional dose of an mRNA COVID-19 vaccine should be administered at least 28 days after completion of the initial 2-dose mRNA COVID-19 vaccine series, based on expert opinion. Whenever possible, complete mRNA COVID-19 vaccination doses (including the primary series and an additional dose) at least two weeks before initiation or resumption of immunosuppressive therapies. Timing of COVID-19 vaccination should take into consideration current or planned immunosuppressive therapies and optimization of both the patient's medical condition and response to vaccine. A patient's clinical team is best positioned to determine the degree of immune compromise and appropriate timing of vaccination. Additional information can be found in the Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html People who are immunocompromised should be counseled about the potential for a reduced immune response to COVID-19 vaccines and the need to continue to follow current prevention measures to protect themselves against COVID-19 until advised otherwise by their healthcare professional.

Response	Consideration
History of heparin-induced thrombocytopenia (HIT)	Although the cause of thrombosis with thrombocytopenia syndrome (TTS) associated with the Janssen COVID-19 Vaccine is unclear, it appears to be similar to another rare immune-mediated syndrome, heparin-induced thrombocytopenia (HIT). Until more information becomes available, experts advise that people with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as HIT, should be offered another COVID-19 vaccine (i.e., mRNA vaccine) if it has been 90 days or less since their illness resolved. After 90 days, patients may be vaccinated with any FDA-authorized COVID-19 vaccine. Experts believe that that following factors do not make people more susceptible to TTS after receipt of the Janssen COVID-19 Vaccine. People with these conditions can be vaccinated with any FDA-authorized COVID-19 vaccine, including the Janssen COVID-19 Vaccine: ■ A prior history of venous thromboembolism ■ Risk factors for venous thromboembolism (e.g., inherited or acquired thrombophilia including Factor V Leiden; prothrombin gene 20210A mutation; antiphospholipid syndrome; protein C, protein S or antithrombin deficiency ■ A prior history of other types of thromboses not associated with thrombocytopenia ■ Pregnancy, post-partum, or receipt of hormonal contraceptives (e.g., combined oral contraceptives, patch, ring) Additional recipient education materials can be found at www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html.
Currently pregnant or breastfeeding	Vaccination is recommended for all people aged 12 years and older, including people that are: ■ Pregnant ■ Breastfeeding ■ Trying to get pregnant now or who might become pregnant in the future A growing body of evidence on the safety and effectiveness of COVID-19 vaccination – in both animal and human studies – indicates that the benefits of vaccination outweigh any known or potential risks of COVID-19 vaccination during pregnancy. If a person becomes pregnant following the first dose of a COVID-19 vaccine that requires two doses (i.e., Pfizer-BioNTech COVID-19 Vaccine or Moderna COVID-19 Vaccine), the second dose should be administered as indicated for the person to be have maximum protection. Pregnant, breastfeeding, and post-partum people 18 through 49 years of age should be aware of the rare risk of TTS after receipt of the Janssen COVID-19 Vaccine and the availability of other FDA-authorized COVID-19 vaccines (i.e., mRNA vaccines).
Have dermal fillers	FDA-authorized COVID-19 vaccines can be administered to people who have received injectable dermal fillers who have no contraindications or precautions for vaccination. Infrequently, these people might experience temporary swelling at or near the site of filler injection (usually the face or lips) following administration of a dose of an COVID-19 vaccine. These people should be advised to contact their healthcare provider if swelling develops at or near the site of dermal filler following vaccination.
History of Guillain-Barré Syndrome	People with a history of GBS can receive any FDA-authorized COVID-19 vaccine. However, given the possible association between the Janssen COVID-19 Vaccine and an increased risk of GBS, a patient with a history of GBS and their clinical team should discuss the availability of mRNA vaccines to offer protection against COVID-19.