CHECKLIST
for storage, handling, and preparation of the Pfizer-BioNTech COVID-19 Vaccine

THREE VACCINE PRESENTATIONS ARE NOW AVAILABLE
Please see the Dosing and Preparation Guide and the Formulation/Presentation Guide for differences in storage, handling, and preparation requirements.

For individuals 12 years of age and older:
DO NOT USE for ages 5 through 11

DILUTE BEFORE USE
vials with purple caps

DO NOT DILUTE
vials with gray caps

For ages 5 through 11 years:
DO NOT USE for 12 years of age and older

DILUTE BEFORE USE
vials with orange caps
("Age 5y to <12y" on vial label)

When prepared according to their respective instructions for use, the FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine for ages 12 years and older (purple cap and gray cap) can be used interchangeably without presenting any safety or effectiveness concerns, but should not be used for individuals 5 through 11 years of age, because of the potential for vaccine administration errors, including dosing errors.

Emergency uses of the vaccine have not been approved or licensed by FDA, but have been authorized by FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in individuals 5 years of age and older. The emergency uses are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

Selected Safety Information
Do not administer to individuals with known history of a severe allergic reaction (eg, anaphylaxis) to any component of the vaccine.

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine.

Monitor vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

Please see Important Safety Information and Indication & Authorized Use on pages 8 and 9.
Before administration of the vaccine, please scroll down and click or visit cvdvaccine-us.com to review the full Prescribing Information and the respective EUA Fact Sheets.
Storage and Handling of the Vaccine and Thermal Shipping Container

**Reminder:** This presentation for ages 12 and older comes in a multiple dose vial that contains 6 doses after dilution.

**Resource materials available on www.cvdvaccine-us.com:**

- EUA Fact Sheet for Vaccination Providers (12 Years & Up) DILUTE BEFORE USE, Purple Cap
- Full Prescribing Information (16 years of age and older) DILUTE BEFORE USE, Purple Cap
- EUA Fact Sheet for Recipients and Caregivers (12 Years & Up)
- Dosing and Preparation Guide
- Dry Ice Replenishment Sheet
- Returning Real-Time Temperature Monitor and Thermal Shipping Container Instructions
- Shipping and Handling Guidelines
- Formulation/Presentation Guide

**Materials checklist for storage and handling:**

- Safety goggles or safety glasses with side shields
- Waterproof insulated gloves
- Box cutter or tool to open box
- Hand truck or dolly to move the thermal shipping container, which can weigh up to ~36 kg (~80 lb)
- Ultra-low-temperature freezer, freezer, or refrigerator; for alternate, temporary storage options available, please visit [https://www.cvdvaccine-us.com](https://www.cvdvaccine-us.com)

Vaccines may be received in medium or single-use thermal shipping containers*

**If using the medium thermal shipping container as temporary storage, you will also need:**

- Dry ice supply (ice pellets 10-16 mm, for re-icing)
- Dry ice scoop
- Temperature-monitoring device
- Packing tape or equivalent
- A method for tracking dry ice replenishment dates to ensure protocol is being followed

*The single-use thermal shipping container cannot be used as temporary storage.

**Before receiving the thermal shipping container, you must have:**

- A well-ventilated room set up to safely handle the thermal shipping container and dry ice
- Proper security so only authorized personnel can access the thermal shipping container contents
- An appropriate area for discarding dry ice so it can sublimate from a solid to a gas
- Access to an occupational health department that can be consulted to ensure appropriate safeguards

Please see Important Safety Information and Indication & Authorized Use on pages 8 and 9. Before administration of the vaccine, please scroll down and click or visit cvdvaccine-us.com to review the full Prescribing Information and the respective EUA Fact Sheets.
Thawing, Dilution, and Preparation

Reminder: This presentation for ages 12 and older comes in a multiple dose vial that contains 6 doses after dilution.

Materials checklist for vaccine preparation:
(Dilute Before Use, 12 years of age and older)

☐ If removing from ultra-low-temperature storage: Personal protective equipment (including waterproof insulated gloves that allow manual dexterity)

☐ Secondary container, such as a small tray, to transport vials removed from original vial carton

☐ 3-mL or 5-mL syringe (for dilution)

☐ 21-gauge or narrower needle (for dilution)

☐ Low dead-volume syringe and/or needle (for administration) appropriate for intramuscular injection

☐ Vials of sterile 0.9% Sodium Chloride Injection, USP (for one-time use)

☐ Antiseptic swabs

☐ Sharps container for disposal

Please see Important Safety Information and Indication & Authorized Use on pages 8 and 9.
Before administration of the vaccine, please click or visit cvdvaccine-us.com to see
Fact Sheets and Prescribing Information for individuals 12 years of age and older

Full Prescribing Information (16 years of age and older) DILUTE BEFORE USE, Purple Cap
Full Prescribing Information (16 years of age and older) DO NOT DILUTE, Gray Cap
EUA Fact Sheet for Vaccination Providers (12 years of age and older), DILUTE BEFORE USE, Purple Cap
EUA Fact Sheet for Vaccination Providers (12 years of age and older), DO NOT DILUTE, Gray Cap
Recipients and Caregivers Fact Sheet (12 years of age and older)

Fact Sheets for individuals 5 through 11 years of age

EUA Fact Sheet for Vaccination Providers (5 through 11 years of age), DILUTE BEFORE USE, Orange Cap
Recipients and Caregivers Fact Sheet (5 through 11 years of age)
**Storage and Handling of the Vaccine and Thermal Shipping Container**

**Reminder:** DO NOT DILUTE. This presentation for ages 12 and older comes in a multiple dose vial that contains 6 doses.

**Resource materials available on www.cvdvaccine-us.com:**

- EUA Fact Sheet for Vaccination Providers (12 Years & Up) - DO NOT DILUTE, Gray Cap
- Full Prescribing Information (16 years of age and older) - DO NOT DILUTE, Gray Cap
- EUA Fact Sheet for Recipients and Caregivers (12 Years & Up)
- Dosing and Preparation Guide
- Dry Ice Replenishment Sheet
- Return Real-Time Temperature Monitor and Thermal Shipping Container Instructions
- Shipping and Handling Guidelines
- Formulation/Presentation Guide

**Materials checklist for storage and handling:**

- Safety goggles or safety glasses with side shields
- Waterproof insulated gloves
- Box cutter or tool to open box
- Hand truck or dolly to move the thermal shipping container, which can weigh up to ~36 kg (~80 lb)
- Ultra-low-temperature freezer* or refrigerator; for alternate, temporary storage options available, please visit https://www.cvdvaccine-us.com

*DO NOT STORE IN STANDARD FREEZER

Vaccines may be received in medium or single-use thermal shipping containers.†

**If using the medium thermal shipping container as temporary storage, you will also need:**

- Dry ice supply (ice pellets 10-16 mm, for re-icing)
- Dry ice scoop
- Temperature-monitoring device
- Packing tape or equivalent
- A method for tracking dry ice replenishment dates to ensure protocol is being followed

† The single-use thermal shipping container cannot be used as temporary storage.

**Before receiving the thermal shipping container, you must have:**

- A well-ventilated room set up to safely handle the thermal shipping container and dry ice
- Proper security so only authorized personnel can access the thermal shipping container contents
- An appropriate area for discarding dry ice so it can sublimate from a solid to a gas
- Access to an occupational health department that can be consulted to ensure appropriate safeguards

Please see Important Safety Information and Indication & Authorized Use on pages 8 and 9. Before administration of the vaccine, please scroll down and click or visit cvdvaccine-us.com to review the full Prescribing Information and the respective EUA Fact Sheets.
Thawing and Preparation

Reminder: DO NOT DILUTE. This presentation for ages 12 and older comes in a multiple dose vial that contains 6 doses.

Materials checklist for vaccine preparation:
(Do Not Dilute, 12 years of age and older)

☐ If removing from ultra-low-temperature storage: Personal protective equipment (including waterproof insulated gloves that allow manual dexterity)

☐ Secondary container, such as a small tray, to transport vials removed from original vial carton

☐ Low dead-volume syringe and/or needle (for administration) appropriate for intramuscular injection

☐ Antiseptic swabs

☐ Sharps container for disposal
Storage and Handling of the Vaccine and Thermal Shipping Container

Reminder: The presentation for ages 5 through 11 comes in a multiple dose vial that contains 10 doses after dilution.

Resource materials available on www.cvdvaccine-us.com:

- EUA Fact Sheet for Vaccination Providers (5 through 11 Years) DILUTE BEFORE USE, Orange Cap
- EUA Fact Sheet for Recipients and Caregivers (5 through 11 years)
- Dosing and Preparation Guide
- Returning Real-Time Temperature Monitor Instructions
- Shipping and Handling Guidelines – Single-Use Thermal Shipping Container
- Formulation/Presentation Guide
- Dry Ice Safety Data Sheet

Materials checklist for storage and handling:

- Safety goggles or safety glasses with side shields
- Waterproof insulated gloves
- Box cutter or tool to open box
- Hand truck or dolly to move the thermal shipping container. Use caution when lifting the thermal shipping container, as it may be heavy
- Ultra-low-temperature freezer* or refrigerator; for alternate, temporary storage options available, please visit https://www.cvdvaccine-us.com
  *DO NOT STORE IN STANDARD FREEZER

Before receiving the thermal shipping container, you must have:

- A well-ventilated room set up to safely handle the thermal shipping container and dry ice
- Proper security so only authorized personnel can access the thermal shipping container contents
- An appropriate area for discarding dry ice so it can sublimate from a solid to a gas
- Access to an occupational health department that can be consulted to ensure appropriate safeguards

Please see Important Safety Information and Indication & Authorized Use on pages 8 and 9. Before administration of the vaccine, please scroll down and click or visit cvdvaccine-us.com to review the full Prescribing Information and the respective EUA Fact Sheets.
Thawing, Dilution, and Preparation

Reminder: The presentation for ages 5 through 11 comes in a multiple dose vial that contains 10 doses after dilution.

Materials checklist for vaccine preparation:
(Dilute Before Use, 5 through 11 years of age)

- If removing from ultra-low-temperature storage: Personal protective equipment (including waterproof insulated gloves that allow manual dexterity)
- Secondary container, such as a small tray, to transport vials removed from original vial carton
- 3-mL or 5-mL syringe (for dilution)
- 21-gauge or narrower needle (for dilution)
- 1 mL low dead-volume syringe and/or needle (for administration) appropriate for intramuscular injection
- Vials of sterile 0.9% Sodium Chloride Injection, USP (for one-time use)
- Antiseptic swabs
- Sharps container for disposal

Please see Important Safety Information and Indication & Authorized Use on pages 8 and 9.
Before administration of the vaccine, please click or visit cvdvaccine-us.com to see
Fact Sheets and Prescribing Information for individuals 12 years of age and older
- Full Prescribing Information (16 years of age and older) DILUTE BEFORE USE, Purple Cap
- Full Prescribing Information (16 years of age and older) DO NOT DILUTE, Gray Cap
- EUA Fact Sheet for Vaccination Providers (12 years of age and older), DILUTE BEFORE USE, Purple Cap
- EUA Fact Sheet for Vaccination Providers (12 years of age and older), DO NOT DILUTE, Gray Cap
- Recipients and Caregivers Fact Sheet (12 years of age and older)
Fact Sheets for individuals 5 through 11 years of age
- EUA Fact Sheet for Vaccination Providers (5 through 11 years of age), DILUTE BEFORE USE, Orange Cap
- Recipients and Caregivers Fact Sheet (5 through 11 years of age)
Important Safety Information and Indication & Authorized Use

Important Safety Information

Do not administer to individuals with known history of a severe allergic reaction (eg, anaphylaxis) to any component of the vaccine.

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine.

Monitor vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.

The vaccine may not protect all vaccine recipients.

Primary Series Adverse Events:

In clinical studies (30 mcg modRNA) of participants 16 through 55 years of age, the most commonly reported adverse reactions (≥10%) were pain at the injection site (88.6%), fatigue (70.1%), headache (64.9%), muscle pain (45.5%), chills (41.5%), joint pain (27.5%), fever (17.8%), and injection site swelling (10.6%).

In clinical studies (30 mcg modRNA) of participants 56 years of age and older, the most commonly reported adverse reactions (≥10%) were pain at the injection site (78.2%), fatigue (56.9%), headache (45.9%), muscle pain (32.5%), chills (24.8%), joint pain (21.5%), injection site swelling (11.8%), fever (11.5%), and injection site redness (10.4%).

In a clinical study (30 mcg modRNA) of adolescents 12 through 15 years of age, adverse reactions following the administration of the primary series included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%).

In a clinical study (10 mcg modRNA) in children 5 through 11 years of age, adverse reactions following administration of any primary series dose included pain at the injection site (84.3%), fatigue (51.7%), headache (38.2%), injection site redness (26.4%), injection site swelling (20.4%), muscle pain (17.5%), chills (12.4%), fever (8.3%), joint pain (7.6%), lymphadenopathy (0.9%), nausea (0.4%), rash (0.3%), malaise (0.1%), and decreased appetite (0.1%).

Booster Dose Adverse Events:

In a clinical study (30 mcg modRNA) of participants 18 through 55 years of age, adverse reactions following administration of a booster dose were pain at the injection site (83.0%), fatigue (63.7%), headache (48.4%), muscle pain (39.1%), chills (29.1%), joint pain (25.3%), lymphadenopathy (5.2%), nausea (0.7%), decreased appetite (0.3%), rash (0.3%), and pain in extremity (0.3%).

Indication & Authorized Use

Indication

COMIRNATY® is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

Interchangeability

The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older (purple cap and gray cap), when prepared according to their respective instructions for use, can be used interchangeably. COMIRNATY® (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine intended for individuals 12 years of age and older (purple cap and gray cap) should not be used for individuals 5 through 11 years of age, because of the potential for vaccine administration errors, including dosing errors.

Authorized Use continued on next page.

Please see additional Important Safety Information and Indication & Authorized Use on pages 8 and 9. Before administration of the vaccine, please scroll down and click or visit cvdvaccine-us.com to review the full Prescribing Information and the respective EUA Fact Sheets.
Important Safety Information and Indication & Authorized Use (cont’d)

Authorized Use

COMIRNATY® (COVID-19 Vaccine, mRNA) is authorized for emergency use to provide:

• a 2-dose 30 mcg modRNA primary series to individuals 12 through 15 years of age
• a third 30 mcg modRNA primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise
• a first 30 mcg modRNA booster dose to individuals 12 years of age and older who have completed a primary series with Pfizer–BioNTech COVID-19 Vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA)
• a first 30 mcg modRNA booster dose to individuals 18 years of age and older who have completed primary vaccination with another authorized or approved COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination
• a second 30 mcg modRNA booster dose to individuals 50 years of age and older who have received a first booster dose of any authorized or approved COVID-19 vaccine; and
• a second 30 mcg modRNA booster dose to individuals 12 years of age and older with certain kinds of immunocompromise and who have received a first booster dose of any authorized or approved COVID-19 vaccine

The Pfizer–BioNTech COVID-19 Vaccine has received Emergency Use Authorization (EUA) from FDA to prevent COVID-19 in individuals 5 years of age and older to provide:

• a 2-dose 10 mcg modRNA primary series to individuals 5 through 11 years of age
• a 2-dose 30 mcg modRNA primary series to individuals 12 years of age and older
• a third 10 mcg modRNA primary series dose to individuals 5 through 11 years of age who have been determined to have certain kinds of immunocompromise
• a third 30 mcg modRNA primary series dose to individuals 12 years of age and older who have certain kinds of immunocompromise
• a first 30 mcg modRNA booster dose to individuals 12 years of age and older who have completed a primary series with Pfizer–BioNTech COVID-19 Vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA)
• a first 30 mcg modRNA booster dose to individuals 18 years of age and older who have completed primary vaccination with another authorized or approved COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination
• a second 30 mcg modRNA booster dose to individuals 50 years of age and older who have received a first booster dose of any authorized or approved COVID-19 vaccine; and
• a second 30 mcg modRNA booster dose to individuals 12 years of age and older with certain kinds of immunocompromise and who have received a first booster dose of any authorized or approved COVID-19 vaccine

Emergency uses of the vaccine have not been approved or licensed by FDA, but have been authorized by FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in individuals 5 years of age and older. The emergency uses are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

Please see Important Safety Information and Indication & Authorized Use on pages 8 and 9.

Before administration of the vaccine, please click or visit cvdvaccine-us.com to see

Fact Sheets and Prescribing Information for individuals 12 years of age and older
Full Prescribing Information (18 years of age and older) DILUTE BEFORE USE, Purple Cap
Full Prescribing Information (16 years of age and older) DO NOT DILUTE, Gray Cap
EUA Fact Sheet for Vaccination Providers (12 years of age and older), DILUTE BEFORE USE, Purple Cap
EUA Fact Sheet for Vaccination Providers (12 years of age and older), DO NOT DILUTE, Gray Cap
Recipients and Caregivers Fact Sheet (12 years of age and older)

Fact Sheets for individuals 5 through 11 years of age
EUA Fact Sheet for Vaccination Providers (5 through 11 years of age), DILUTE BEFORE USE, Orange Cap
Recipients and Caregivers Fact Sheet (5 through 11 years of age)
The Pfizer-BioNTech COVID-19 Vaccine, which is based on BioNTech proprietary mRNA technology, was developed by both BioNTech and Pfizer.