CHECKLIST

for storage, handling, and preparation of the Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY® (COVID-19 Vaccine, mRNA)*

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*The licensed COMIRNATY® vaccine has the same formulation as the authorized vaccine Pfizer-BioNTech COVID-19 Vaccine, and they can be used interchangeably without presenting any safety or effectiveness concerns. Although they may be manufactured in different facilities, the products offer the same safety and effectiveness.

The 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) for use in individuals 12 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

Known history of a severe allergic reaction (eg, anaphylaxis) to any component of COMIRNATY® is a contraindication.

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).

Global: Drives to http://labeling.pfizer.com/ShowLabeling.aspx?id=15623

Please see Important Safety Information and Indication & Authorized Use on pages 4 and 5.

Before administration of the vaccine, please see full Prescribing Information (16+ years of age), EUA Fact Sheet for Vaccination Providers (12+ years of age), and Recipients and Caregivers Fact Sheet (12+ years of age).

BIONTECH Pfizer

Global: Drives to http://labeling.pfizer.com/ShowLabeling.aspx?id=14471&format=pdf

Global: Drives to http://labeling.pfizer.com/ShowLabeling.aspx?id=14472&format=pdf

eua-2021-5683-0952231

Storage and Handling of the Vaccine and Thermal Shipping Container

Reminder: The vaccine comes in a multiple dose vial that contains 6 doses after dilution.

Review the following instructional materials on www.cvdvaccine-us.com:

- ☐ EUA Fact Sheet for Vaccination Providers (12 years of age and older)
- ☐ Full Prescribing Information (16 years of age and older)
- ☐ EUA Fact Sheet for Recipients and Caregivers (12 years of age and older)
- ☐ How to Administer Guide
- ☐ Low Dead-Volume Syringes and/or Needles Information Sheet
- ☐ Dry Ice Replenishment Instructions
- ☐ Thermal Shipping Container Return Instructions
- ☐ Shipping & Handling Guidelines
- ☐ Vaccine Dosing 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

For 195-pack cartons only, if using the 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

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
- ☐ An appropriate area for discarding dry ice so it can sublimate from a solid to a gas
- ☐ A method for tracking dry ice replenishment dates to ensure protocol is being followed (if using the thermal shipping container as temporary storage)
- ☐ Proper security so only authorized personnel can access the thermal shipping container contents
- ☐ 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 4 and 5.
Before administration of the vaccine, please see full Prescribing Information (16+ years of age), EUA Fact Sheet for Vaccination Providers (12+ years of age), and Recipients and Caregivers Fact Sheet (12+ years of age).

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MULTIPLE DOSE VIAL

Thawing, Dilution, and Preparation

Reminder: The vaccine comes in a multiple dose vial that contains 6 doses after dilution.

Materials checklist for vaccine preparation:

- ☐ Secondary container, such as a small tray, to transport vials removed from original vial carton
- ☐ Refrigerator (for thawing and to maintain thawed vaccine vials for up to 1 month at a temperature of 2°C to 8°C [35°F to 46°F])
- ☐ 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
- ☐ Personal protective equipment (including gloves that allow manual dexterity)
- ☐ Vials of 0.9% Sodium Chloride Injection, USP (for one-time use)
- ☐ Vaccine vials
- ☐ Antiseptic swabs
- ☐ Sharps container for disposal

Current as of October 5, 2021. For the most up-to-date version, visit www.cvdvaccine-us.com.

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Before administration of the vaccine, please see full Prescribing Information (16+ years of age), EUA Fact Sheet for Vaccination Providers (12+ years of age), and Recipients and Caregivers Fact Sheet (12+ years of age).

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Important Safety Information and Indication & Authorized Use

Important Safety Information

Known history of a severe allergic reaction (eg, anaphylaxis) to any component of COMIRNATY® is a contraindication.

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.

Syncope (fainting) may occur in association with administration of injectable vaccines, including this vaccine. 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.

In clinical studies 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 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 evaluating administration of a booster dose in participants 18 through 55 years of age, the most commonly reported adverse reactions (≥10%) following the dose were pain at the injection site (83.0%), fatigue (63.7%), headache (48.4%), muscle pain (39.1%), chills (29.1%), and joint pain (25.3%).

In a clinical study of adolescents 12 through 15 years of age, the most commonly reported adverse reactions included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), 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%).

Indication & Authorized Use

The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.

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.

Authorized Use

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

- a two-dose primary series in individuals 12 through 15 years
- a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a single booster dose in individuals:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19
  - 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

Authorized Use information continued on next page.

Before administration of the vaccine, please see full Prescribing Information (16+ years of age), EUA Fact Sheet for Vaccination Providers (12+ years of age), and Recipients and Caregivers Fact Sheet (12+ years of age).

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Important Safety Information and Indication & Authorized Use (cont'd)

Authorized Use (cont'd)

The Pfizer-BioNTech COVID-19 Vaccine has received Emergency Use Authorization (EUA) from FDA to prevent COVID-19 in individuals 12 years of age and older to provide:

- a two-dose primary series in individuals 12 years of age and older
- a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a single booster dose in individuals:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19
  - 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

The 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) for use in individuals 12 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.

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Manufactured for
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55131 Mainz, Germany
Marketing Authorization Holder

Manufactured by
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New York, NY 10017

The Pfizer-BioNTech COVID-19 Vaccine, which is based on BioNTech proprietary mRNA technology, was developed by both BioNTech and Pfizer.