Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)

Emergency Use Authorization
Emergency uses of the vaccines 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 aged 6 months and older for the Pfizer-BioNTech COVID-19 Vaccine and 12 years and older for the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. 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 EUA Fact Sheets at www.cvdvaccine-us.com.

Help Avoid Administration Errors
Because of the potential for vaccine administration errors, including dosing errors, vaccine presentations should only be used for the ages specified on the vial labels, cartons, or the respective age-based Fact Sheet. The information in the Fact Sheets supersedes the information printed on the vial labels and cartons.

Selected Safety Information
Do not administer Pfizer-BioNTech COVID-19 Vaccine, COMIRNATY (COVID-19 Vaccine, mRNA), or Pfizer-BioNTech COVID-19 Vaccine, Bivalent to individuals with known history of a severe allergic reaction (eg, anaphylaxis) to any component of these vaccines.

Management of Acute Allergic Reactions
Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine, COMIRNATY, or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

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).
Pfizer-BioNTech COVID-19 Vaccine, Bivalent is authorized for use in individuals 12 years of age and older as a single booster dose administered at least 2 months after either\textsuperscript{1,2}:

- Completion of primary vaccination with any authorized or approved monovalent* COVID-19 vaccine, or
- Receipt of the most recent booster dose with any authorized or approved monovalent* COVID-19 vaccine

*Monovalent refers to any authorized or approved COVID-19 vaccine that contains or encodes the spike protein of only the Original SARS-CoV-2.

Selected Safety Information

**Myocarditis and Pericarditis**

Myocarditis and pericarditis have been reported following administration of Pfizer-BioNTech COVID-19 Vaccine. Postmarketing safety data with Pfizer-BioNTech COVID-19 Vaccine are relevant to Pfizer-BioNTech COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process.

Postmarketing data with authorized or approved monovalent mRNA COVID-19 vaccines demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following receipt of the second primary series dose or first booster dose, with most booster doses likely administered at least 5 months after completing primary vaccination. For the Pfizer-BioNTech COVID-19 Vaccine, the observed risk is higher among adolescent males and adult males under 40 years of age than among females and older males, and 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).
**Distinguishing Between Gray Cap Vials:**

**Pfizer-BioNTech COVID-19 Vaccine, Bivalent** has the same storage, handling, preparation, dose volume, and administration instructions as **Pfizer-BioNTech COVID-19 Vaccine gray cap vials and COMIRNATY gray cap vials,** all of which **MUST NOT BE DILUTED.**

### Key Steps
1. Confirm that the patient is 12 years of age or older.
2. Is the patient eligible for a primary series dose or a booster dose?
3. To help avoid dosing errors, use the table to the right to verify the vials (including labels) prior to preparation and administration.

### Primary Series

<table>
<thead>
<tr>
<th>Name</th>
<th>COMIRNATY® (COVID-19 Vaccine, mRNA)*</th>
<th>Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Variant Composition</strong></td>
<td>Monovalent: 30 mcg modRNA-Original</td>
<td>Bivalent: 15 mcg modRNA-Original and 15 mcg modRNA-Omicron BA.4/BA.5</td>
</tr>
<tr>
<td><strong>Authorized Use (AU) or Indication</strong></td>
<td>Primary Series AU: as a 2-dose primary series to individuals 12 years of age and older; and a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise†</td>
<td>Primary Series AU: as a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise†</td>
</tr>
<tr>
<td><strong>Cap Color &amp; Label</strong></td>
<td>Pfizer-BioNTech COVID-19 Vaccine NDC number: Multiple Dose Vial: 59267-1025-1</td>
<td>COMIRNATY® (COVID-19 Vaccine, mRNA) NDC number: Multiple Dose Vial: 0069-2025-01</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) NDC number: Multiple Dose Vial: 59267-0304-1</td>
</tr>
</tbody>
</table>

*When prepared according to their respective instructions for use, the FDA-approved COMIRNATY and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older can be used interchangeably without presenting any safety or effectiveness concerns.

†Certain kinds of immunocompromise refers to individuals who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

### Selected Safety Information

**Syncope**

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.

**Altered Immunocompetence**

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to Pfizer-BioNTech COVID-19 Vaccine, COMIRNATY, or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

**Limitation of Effectiveness**

Pfizer-BioNTech COVID-19 Vaccine, COMIRNATY, or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent may not protect all vaccine recipients.

Please see additional Important Safety Information throughout and full Important Safety Information and Indication & Authorized Use on pages 5 through 7. Before administration, please scroll down and click or visit cvdvaccine-us.com to review the full Prescribing Information (COMIRNATY Purple Cap or Gray Cap) and respective Pfizer-BioNTech COVID-19 Vaccine or Pfizer-BioNTech COVID-19 Vaccine, Bivalent EUA Fact Sheets.
To help avoid dosing errors, verify the vials (including labels) prior to preparation and administration.

Pfizer-BioNTech COVID-19 Vaccine
NDC number: Multiple Dose Vial: 59267-1025-1

COMIRNATY® (COVID-19 Vaccine, mRNA)
NDC number: Multiple Dose Vial: 0069-2025-01

Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)
NDC number: Multiple Dose Vial: 59267-0304-1

Please see additional Important Safety Information throughout and full Important Safety Information and Indication & Authorized Use on pages 5 through 7. Before administration, please scroll down and click or visit cvd vaccine-us.com to review the full Prescribing Information (COMIRNATY Purple Cap or Gray Cap) and respective Pfizer-BioNTech COVID-19 Vaccine or Pfizer-BioNTech COVID-19 Vaccine, Bivalent EUA Fact Sheets.
COMIRNATY (COVID-19 Vaccine, mRNA)

**Indication & Authorized Use**

COMIRNATY® (COVID-19 Vaccine, mRNA) 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 12 years of age and older. It is also authorized for emergency use to provide a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise.

**Pfizer-BioNTech COVID-19 Vaccine**

**Authorized Use**

Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 6 months of age and older.

**Interchangeability (Primary Series for Individuals 12 Years of Age and Older)**

When prepared according to their respective instructions for use, the FDA-approved COMIRNATY and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older can be used interchangeably without presenting any safety or effectiveness concerns. Because of the potential for vaccine administration errors, including dosing errors, vaccine presentations should only be used for the ages specified on the vial labels, cartons, or the respective age-based Fact Sheet. The information in the Fact Sheets supersedes the information printed on the vial labels and cartons.

**Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)**

**Authorized Use**


**Important Safety Information**

Do not administer Pfizer-BioNTech COVID-19 Vaccine, COMIRNATY, or Pfizer-BioNTech COVID-19 Vaccine, Bivalent to individuals with known history of a severe allergic reaction (eg, anaphylaxis) to any component of these vaccines.

**Management of Acute Allergic Reactions**

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine, COMIRNATY, or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. 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).

**Myocarditis and Pericarditis**

Myocarditis and pericarditis have been reported following administration of Pfizer-BioNTech COVID-19 Vaccine. Postmarketing safety data with Pfizer-BioNTech COVID-19 Vaccine are relevant to Pfizer-BioNTech COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process.

Postmarketing data with authorized or approved monovalent mRNA COVID-19 vaccines demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following receipt of the second primary series dose or first booster dose, with most booster doses likely administered at least 5 months after completing primary vaccination. For the Pfizer-BioNTech COVID-19 Vaccine, the observed risk is higher among adolescent males and adult males under 40 years of age than among females and older males, and 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).

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Syncope

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.

Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to Pfizer-BioNTech COVID-19 Vaccine, COMIRNATY (COVID-19 Vaccine, mRNA), or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

Limitation of Effectiveness

Pfizer-BioNTech COVID-19 Vaccine, COMIRNATY, or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent may not protect all vaccine recipients.

Adverse Reactions

Primary Series Adverse Events: Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY

In clinical studies (30 mcg modRNA) of adolescents 12 through 15 years of age, the most commonly reported adverse reactions (≥8%) were 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%), and injection site redness (8.6%).

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%).

Booster Dose Adverse Events: Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY

In a clinical study (30 mcg modRNA) of participants 18 through 55 years of age, adverse reactions following administration of a first 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%).

Booster Dose Adverse Events: Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)

The safety of a booster dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent is based on:

• safety data from a clinical study which evaluated a booster dose of Pfizer-BioNTech's bivalent COVID-19 vaccine (Original and Omicron BA.1), not authorized or approved, hereafter referred to as bivalent vaccine (Original and Omicron BA.1),
• safety data from clinical trials which evaluated primary and booster vaccination with Pfizer-BioNTech COVID-19 Vaccine, and
• post marketing safety data with Pfizer-BioNTech COVID-19 Vaccine.

The safety data accrued with the bivalent vaccine (Original and Omicron BA.1) and with Pfizer-BioNTech COVID-19 Vaccine are relevant to Pfizer-BioNTech COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process.

The clinical study that evaluated a booster dose of the bivalent vaccine (Original and Omicron BA.1) included participants 55 years of age and older. Adverse reactions following administration of the bivalent vaccine (Original and Omicron BA.1) as a second booster dose included pain at the injection site (58.1%), fatigue (48.2%), headache (33.6%), muscle pain (22.3%), chills (13.0%), joint pain (11.3%), injection site redness (7.0%), injection site swelling (6.6%), fever (5.0%), lymphadenopathy (0.3%), nausea (0.3%), and malaise (0.3%).

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In a clinical study of participants 18 through 55 years of age, adverse reactions following administration of a first booster dose of Pfizer-BioNTech COVID-19 Vaccine 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 (9.2%), nausea (0.7%), decreased appetite (0.3%), rash (0.3%), and pain in extremity (0.3%).

Post Authorization Experience
Severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (eg, rash, pruritus, urticaria, angioedema), diarrhea, vomiting, pain in extremity (arm), and syncope have been reported following administration of the Pfizer–BioNTech COVID-19 Vaccine.

Myocarditis and pericarditis have been reported following administration of the Pfizer–BioNTech COVID-19 Vaccine.

Additional adverse reactions, some of which may be serious, may become apparent with post authorization use of these vaccines.