Dosing schedule for ages 12 years and older with Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)

Individuals 12 Years & Older	
Vaccination History With a Monovalent COVID-19 Vaccine	**Dosing Schedule With Pfizer-BioNTech COVID-19 Vaccine, Bivalent**
Unvaccinated	**Single dose**
Previously vaccinated with one or more doses of a monovalent COVID-19 vaccine	**Single dose** • At least 2 months after any monovalent COVID-19 vaccine

Additional recommendations for people 5 years of age & older with certain kinds of immunocompromise and for those aged 65 years & older

Individuals 65 years of age and older who have received one dose of a bivalent COVID-19 vaccine:
A dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent may be administered at least 4 months after the dose of the bivalent COVID-19 vaccine.

Immunocompromised individuals 5 years of age and older who have received one dose of a bivalent COVID-19 vaccine:
An additional dose with Pfizer-BioNTech COVID-19 Vaccine, Bivalent may be administered at least 2 months following the dose of the bivalent COVID-19 vaccine; additional doses may be administered at the discretion of the healthcare provider.

The Pfizer-BioNTech COVID-19 Vaccine, a monovalent vaccine, encodes the spike protein of only the Original SARS-CoV-2.
The monovalent Pfizer-BioNTech COVID-19 Vaccine is no longer authorized for use in the United States.

Pfizer-BioNTech COVID-19 Vaccine, Bivalent has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals aged 6 months of age and older. The emergency use of this product is 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.

Authorized Use and Important Safety Information

AUTHORIZED USE

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

IMPORTANT SAFETY INFORMATION

Tell your vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects the immune system
- are pregnant, plan to become pregnant, or are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

Please click for Pfizer-BioNTech COVID-19 Vaccine, Bivalent
Vaccination Provider and **Recipient and Caregiver** EUA Fact Sheets.

Pfizer   BIONTECH

Authorized Use and Important Safety Information

AUTHORIZED USE

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

IMPORTANT SAFETY INFORMATION

Tell your vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects the immune system
- are pregnant, plan to become pregnant, or are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

- The vaccine may not protect everyone

- A person should **NOT** get Pfizer-BioNTech COVID-19 Vaccine, Bivalent if they have had a severe allergic reaction after a previous dose of Pfizer-BioNTech COVID-19 Vaccine*, Pfizer-BioNTech COVID-19 Vaccine, Bivalent, or COMIRNATY® (COVID-19 Vaccine, mRNA) or to any ingredients in these vaccines

- There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received the vaccine for monitoring after vaccination. If you experience a severe allergic reaction, call 9-1-1 or go to the nearest hospital

Seek medical attention right away if you have any of the following symptoms:

- difficulty breathing, swelling of the face and throat, a fast heartbeat, a bad rash all over the body, dizziness, or weakness

*Monovalent formulation is no longer authorized for use in the United States.

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received Pfizer-BioNTech COVID-19 Vaccine, Bivalent, Pfizer-BioNTech COVID-19 Vaccine, or COMIRNATY (COVID-19 Vaccine, mRNA), more commonly in adolescent males and adult males under 40 years of age than among females and older males. In most of these people, symptoms began within a few days following vaccination. The chance of having this occur is very low. **Seek medical attention right away if you or your child have any of the following symptoms after receiving the vaccine, particularly during the 2 weeks after receiving a vaccine:**

- Chest pain
- Shortness of breath or difficulty breathing
- Feelings of having a fast-beating, fluttering, or pounding heart

Additional symptoms, particularly in children, may include:

- Fainting
- Unusual and persistent irritability
- Unusual and persistent poor feeding
- Unusual and persistent fatigue or lack of energy
- Persistent vomiting
- Persistent pain in the abdomen
- Unusual and persistent cool, pale skin

- Fainting can happen after getting injectable vaccines, including Pfizer-BioNTech COVID-19 Vaccine, Bivalent. For this reason, your vaccination provider may ask you to stay at the place where you received the vaccine for monitoring after vaccination

- People with weakened immune systems may have a reduced immune response to Pfizer-BioNTech COVID-19 Vaccine, Bivalent

**Please click for Pfizer-BioNTech COVID-19 Vaccine, Bivalent
<u>Vaccination Provider</u> and <u>Recipient and Caregiver</u> EUA Fact Sheets.**

Authorized Use and Important Safety Information (cont'd)

Side effects that have been reported with Pfizer-BioNTech COVID-19 Vaccine, Bivalent, Pfizer-BioNTech COVID-19 Vaccine, or COMIRNATY (COVID-19 Vaccine, mRNA) include:

- Severe allergic reactions
- Non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Injection site pain/tenderness
- Tiredness
- Headache
- Muscle pain
- Chills
- Joint pain
- Fever
- Injection site swelling
- Injection site redness
- Nausea
- Feeling unwell
- Swollen lymph nodes (lymphadenopathy)
- Decreased appetite
- Diarrhea
- Vomiting
- Arm pain
- Fainting in association with injection of the vaccine
- Dizziness
- Irritability

These may not be all the possible side effects. Serious and unexpected side effects may occur. Call the vaccination provider or healthcare provider about bothersome side effects or side effects that do not go away.

- Individuals should always ask their healthcare providers for medical advice about adverse events. Report vaccine side effects to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to www.vaers.hhs.gov/reportevent.html. In addition, individuals can report side effects to Pfizer Inc. at www.pfizersafetyreporting.com or by calling 1-800-438-1985

Please click for Pfizer-BioNTech COVID-19 Vaccine, Bivalent <u>Vaccination Provider</u> and <u>Recipient and Caregiver</u> EUA Fact Sheets.