

# Select Information Related to Dosing Intervals for the Pfizer–BioNTech COVID-19 Vaccine

May 2022

## FDA APPROVED FOR 16 YEARS OF AGE AND OLDER

In individuals 16 years of age and older, COMIRNATY® (COVID-19 Vaccine, mRNA)\* has been approved for active immunization to prevent COVID-19 caused by SARS-CoV-2. COMIRNATY® (COVID-19 Vaccine, mRNA) is also known as the Pfizer–BioNTech COVID-19 Vaccine.

## AUTHORIZED FOR EMERGENCY USE

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 EUA Fact Sheets at [www.cvdvaccine-us.com](http://www.cvdvaccine-us.com).

\*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.

## 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 additional Important Safety Information and Indication & Authorized Use on pages 6 and 7.**

**Before administration of the vaccine, please scroll down and click or visit [cvdvaccine-us.com](http://cvdvaccine-us.com) to review the full Prescribing Information and the respective EUA Fact Sheets.**



# Pfizer-BioNTech COVID-19 Vaccine Primary Series Interval

**NOTE:** For some populations, FDA-approved/authorized dosing intervals differ from CDC Interim Clinical Considerations for Use of COVID-19 Vaccines in the US, as specified below.

## EUA Fact Sheets for Vaccination Providers: Dosing Intervals for Primary Series for the Eligible General Population<sup>1-3</sup>

The Pfizer-BioNTech COVID-19 Vaccine is FDA-authorized in people ages 5 years and older as a 2-dose primary series, with an interval of 3 weeks between doses.

Primary vaccination	Age	Primary series
Pfizer-BioNTech	5-11 years	3 weeks
Pfizer-BioNTech	≥12 years	3 weeks

### Selected Safety Information

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%), 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%).

**Please see additional Important Safety Information and Indication & Authorized Use on pages 6 and 7. Before administration of the vaccine, please scroll down and click or visit [cvdvaccine-us.com](https://www.cvdvaccine-us.com) to review the full Prescribing Information and the respective EUA Fact Sheets.**

# Pfizer-BioNTech COVID-19 Vaccine Primary Series Interval (cont'd)

**NOTE:** For some populations, FDA-approved/authorized dosing intervals differ from CDC Interim Clinical Considerations for Use of COVID-19 Vaccines in the US, as specified below.

## Select CDC Considerations for Intervals for mRNA COVID-19 Vaccine Primary Series<sup>4\*</sup>

- The Pfizer-BioNTech COVID-19 Vaccine is FDA-approved or authorized for a 3-week interval between the first and second dose
- A 3-week interval continues to be the recommended interval for people who are moderately or severely immunocompromised, adults ages 65 years and older, and in situations when the fullest possible protection needs to be achieved sooner (eg, increased concern about COVID-19 community levels or an individual's higher risk for severe disease)
- mRNA COVID-19 vaccines are safe and effective at the FDA-approved or FDA-authorized intervals, but a longer interval may be considered for some populations
- While absolute risk remains small, the risk for myocarditis is higher for males ages 12-39 years, and this risk might be reduced by extending the interval between the first and second dose
- Some studies in adolescents (ages 12-17 years) and adults have shown the small risk of myocarditis associated with mRNA COVID-19 vaccines might be reduced and peak antibody responses and vaccine effectiveness may be increased with an interval longer than 4 weeks. Extending the interval beyond 8 weeks has not been shown to provide additional benefit
- There are currently no data available for children ages 11 years and younger
- **In summary, an 8-week interval may be optimal for people who are not moderately or severely immunocompromised and ages 12-64 years, especially for males ages 12-39 years**

Primary vaccination	Age group	Number of doses in primary series	Interval between 1st and 2nd dose
Pfizer-BioNTech	5-11 years	2	3 weeks
Pfizer-BioNTech	≥12 years	2	3-8 weeks <sup>†</sup>

\*For the vaccination schedule for people who are moderately or severely immunocompromised, see table on the following page.

<sup>†</sup>An **8-week** interval may be optimal for some people ages 12 years and older, especially for males ages 12 to 39 years. A **shorter interval** (3 weeks for Pfizer-BioNTech) between the first and second doses remains the recommended interval for people who are moderately to severely immunocompromised, adults ages 65 years and older, and in situations in which there is increased concern about COVID-19 community levels or an individual's higher risk of severe disease.

Information and table adapted from CDC Interim Clinical Considerations dated 04/21/2022.

For more information please refer to the [CDC Interim Clinical Considerations](#)

[By clicking this link, you will be redirected to a website that is neither owned nor controlled by Pfizer. Pfizer is not responsible for the content or services of this site.]

Additionally, please see the Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheets for Vaccination Providers at <https://www.cvdvaccine-us.com>

## Selected Safety Information

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%).

Please see additional Important Safety Information and Indication & Authorized Use on pages 6 and 7. Before administration of the vaccine, please **scroll down** and click or visit [cvdvaccine-us.com](https://www.cvdvaccine-us.com) to review the full Prescribing Information and the respective EUA Fact Sheets.

# Pfizer-BioNTech COVID-19 Vaccination for People With Moderate or Severe Immunocompromise

**NOTE:** For some populations, FDA-approved/authorized dosing intervals differ from CDC Interim Clinical Considerations for Use of COVID-19 Vaccines in the US, as specified below.

## EUA Fact Sheets for Vaccination Providers: Dosing Intervals for the Eligible Immunocompromised Population<sup>1-3\*</sup>

**EUA Fact Sheets** state a **third primary series dose** of the vaccine at least 28 days following the second dose is authorized for administration to individuals **5 years of age and older** who have undergone **solid organ transplantation**, or who are diagnosed with conditions that are considered to have an **equivalent level of immunocompromise**.

\*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.

Primary vaccination	Age group	Authorized/ Recommended primary series doses	Authorized/ Recommended interval between dose 1 and dose 2	Authorized/ Recommended interval between dose 2 and dose 3
Pfizer-BioNTech	5-11 years	3	3 weeks	≥28 days following the second dose <sup>†</sup>
Pfizer-BioNTech	≥12 years	3	3 weeks	≥28 days following the second dose <sup>‡</sup>

EUA Fact Sheets authorize a first booster dose for individuals 12 years of age and older at least 5 months after completing a primary series, without distinguishing among individuals based on risk. EUA Fact Sheets authorize a second booster dose for individuals 50 years of age and older and select individuals 12 years of age with certain types of immunocompromise at least 4 months after receipt of a first booster dose.

<sup>†</sup>At least 28 days following the second dose is authorized for administration to individuals 5 through 11 years of age who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

<sup>‡</sup>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.

For more information please refer to the [CDC Interim Clinical Considerations](#)

[By clicking this link, you will be redirected to a website that is neither owned nor controlled by Pfizer. Pfizer is not responsible for the content or services of this site.]

Additionally, please see the Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheets for Vaccination Providers at <https://www.cvdvaccine-us.com>

## Selected Safety Information

### 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%).

Please see additional Important Safety Information and Indication & Authorized Use on pages 6 and 7. Before administration of the vaccine, please **scroll down** and click or visit [cvdvaccine-us.com](https://www.cvdvaccine-us.com) to review the full Prescribing Information and the respective EUA Fact Sheets.

# Pfizer-BioNTech COVID-19 Vaccination for People With Moderate or Severe Immunocompromise

**NOTE:** For some populations, FDA-approved/authorized dosing intervals differ from CDC Interim Clinical Considerations for Use of COVID-19 Vaccines in the US, as specified below.

## Select CDC Considerations for Intervals for mRNA COVID-19 Vaccine Primary Series for Moderately or Severely Immunocompromised Individuals<sup>4\*</sup>

For people **12 years of age and older** with **moderate or severe immunocompromise** who received an mRNA vaccine primary series, the **CDC recommends a booster dose at least 3 months** after the third dose in the primary series, **for a total of 4 doses**,\* preferably with an mRNA COVID-19 Vaccine.

Primary vaccination	Age group	Number of primary vaccine doses	Number of booster doses	Interval between 1st and 2nd dose	Interval between 2nd and 3rd dose	Interval between 3rd and 4th dose
Pfizer-BioNTech	5-11 years	3	NA	3 weeks	At least 4 weeks	NA
Pfizer-BioNTech	12 years and older	3	1*	3 weeks	At least 4 weeks	At least 3 months*

\*People ages 12 years and older may choose to receive a second booster dose using an mRNA COVID-19 vaccine if it has been at least 4 months after the first booster dose, for a total of 5 doses.

Other factors that moderately or severely immunocompromised people might consider for getting the second booster dose as soon as possible include:

- Presence of other underlying medical conditions that increase the risk of severe COVID-19 disease
- Living with someone who is at increased risk for severe disease or who cannot be vaccinated due to age or contraindication
- Increased risk of exposure to SARS-CoV-2, such as through occupational, institutional, or other activities (eg, travel or large gatherings)
- Living or working in or near an area where the COVID-19 community level is medium or high or traveling to such an area

Factors that moderately or severely immunocompromised people might consider for waiting to get a second booster dose include:

- SARS-CoV-2 infection within the last 3 months
- Hesitancy about getting another recommended booster dose in the future, as a booster dose may be more important in the fall and/or if a variant-specific vaccine is needed

Information and table adapted from CDC Interim Clinical Considerations dated 04/21/2022.

## 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 additional Important Safety Information and Indication & Authorized Use on pages 6 and 7. Before administration of the vaccine, please scroll down and click or visit [cvdvaccine-us.com](https://www.cvdvaccine-us.com) to review the full Prescribing Information and the respective EUA Fact Sheets.**

# Important Safety Information and Indication & Authorized Use

## 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

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 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

*Important Safety Information continued on next page.*

**Before administration of the vaccine, please scroll down and click or visit [cvdvaccine-us.com](https://www.cvdvaccine-us.com) to review the full Prescribing Information and the respective EUA Fact Sheets.**

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

## 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 ( $\geq 10\%$ ) 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 ( $\geq 10\%$ ) 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%), 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%).

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%).

**Please see Indication & Authorized Use on page 6.**

**Before administration of the vaccine, please click or visit [covidvaccine-us.com](https://covidvaccine-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 \(5 through 11 years of age\)](#)

**References:** **1.** Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)(12 years of age and older), DILUTE BEFORE USE, Purple Cap. Pfizer and BioNTech; March 29, 2022. **2.** Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)(12 years of age and older), DO NOT DILUTE, Gray Cap. Pfizer and BioNTech; March 29, 2022. **3.** Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)(5 through 11 years of age), DILUTE BEFORE USE, Orange Cap. Pfizer and BioNTech; January 03, 2022. **4.** Use of COVID-19 vaccines in the United States. Accessed March 15, 2022. <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>

**BIONTECH**



Manufactured for  
BioNTech Manufacturing GmbH  
An der Goldgrube 12  
55131 Mainz, Germany  
Marketing Authorization Holder

Manufactured by  
Pfizer Inc.  
New York, NY 10017