

PFIZER

COVID-19 vaccine, also known as COMIRNATY® IVR & Live Operator Script Greetings

PP-CVV-USA-0426

877-829-2619 (877-VAX-CO19)

1.0 Live Operator Script Welcome for PP-CVV-USA-0303

1.0 New Greeting 1.1

Good (Morning/Afternoon/Evening) and thank you for calling the customer service center for the Pfizer-BioNTech COVID-19 vaccine, also known as COMIRNATY® (COVID-19 Vaccine, mRNA).

*The licensed COMIRNATY® vaccine has the same formulation as the authorized vaccine Pfizer-BioNTech Covid-19 Vaccine, and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct, with certain differences that do not impact safety or 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.

My name is _____. How may I help you today?

Before we continue, I need to share the following important safety information with you...

INDICATION & AUTHORIZED USE

HOW IS THE VACCINE GIVEN?

The vaccine will be given to you as an injection into the muscle.

Primary Series: The vaccine is administered as a 2-dose series, 3 weeks apart. A third dose may be administered at least 4 weeks after the second dose to individuals who are determined to have certain kinds of immunocompromise.

Booster Dose: A single booster dose of the vaccine may be administered to 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

WHAT IS THE INDICATION AND AUTHORIZED USE?

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

COMIRNATY® (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech.

- It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older
- It is also authorized under EUA to provide:

This is an update to PP-CVV-USA-0303, Section 1.0 Greeting and replaces PP-CVV-USA-0378-01 Section 1.0. Only the updated section has been submitted. Please see live operator map on page 7 for a detailed explanation of the section that has been updated and PP-CVV-USA-0303 for the remaining pages. PP-CVV-USA-0303 has been submitted to CBER with a copy to APLB on 08/04/2021

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877-829-2619 (877-VAX-CO19)

- 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

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to provide:

- a two-dose primary series in individuals 12 years of age and older
- a third primary series dose for 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

IMPORTANT SAFETY INFORMATION

You should **not** get the vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

Tell the 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 your 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.

Side effects reported with the vaccine include:

- 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 your vaccine for monitoring after vaccination
 - Signs of a severe allergic reaction can include difficulty breathing, swelling of your face and throat, a fast heartbeat, a bad rash all over your body, dizziness, and weakness
 - If you experience a severe allergic reaction, call 9-1-1 or go to the nearest hospital

PFIZER

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- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of the vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the vaccine:
 - chest pain
 - shortness of breath
 - feelings of having a fast-beating, fluttering, or pounding heart
- Side effects that have been reported with the vaccine 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; 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
- These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials. Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away

Data on administration of this vaccine at the same time as other vaccines have not yet been submitted to FDA. If you are considering receiving this vaccine with other vaccines, discuss your options with your healthcare provider.

Patients should always ask their healthcare providers for medical advice about adverse events. Report negative side effects of vaccines to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Visit <http://www.vaers.hhs.gov> or call 1-800-822-7967. In addition, you can report side effects to Pfizer Inc. at www.pfizersafetyreporting.com or by calling 1-800-438-1985.

For the most recent 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) please visit www.Comirnaty.com

PP-CVV-USA-0426-01

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PP-CVV-USA-0426

877-829-2619 (877-VAX-CO19)

1.0 IVR Script Welcome and 1.1 Welcome Transfers from Pfizer Trade IVR for PP-CVV-0304

New Greeting
callrecording

This is an update to PP-CVV-USA-0304, Section 1.0 Welcome and 1.1 Welcome Transfers from Pfizer Trade IVR and replaces PP-CVV-USA-0378-02 Section 1.0 IVR Script Welcome and 1.1 Welcome Transfers from Pfizer Trade IVR for PP-CVV-USA-0304. Only the updated section has been submitted. Please see live operator map on page 8 for a detailed explanation of the section that has been updated and PP-CVV-USA-0304 for the remaining pages. PP-CVV-USA-0304 has been submitted to CBER with a copy to APLB on 08/04/2021

Thank you for calling the customer service center for the Pfizer-BioNTech COVID-19 vaccine, also known as COMIRNATY® (COVID-19 Vaccine, mRNA).

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INDICATION & AUTHORIZED USE

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The vaccine will be given to you as an injection into the muscle.

Primary Series: The vaccine is administered as a 2-dose series, 3 weeks apart. A third dose may be administered at least 4 weeks after the second dose to individuals who are determined to have certain kinds of immunocompromise.

Booster Dose: A single booster dose of the vaccine may be administered to individuals:

- 65 years of age and older
- 18 through 64 years of age at high risk of severe COVID-19
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WHAT IS THE INDICATION AND AUTHORIZED USE?

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PFIZER

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PP-CVV-USA-0426

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- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your 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.

Side effects reported with the vaccine include:

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 - 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 your vaccine for monitoring after vaccination
 - Signs of a severe allergic reaction can include difficulty breathing, swelling of your face and throat, a fast heartbeat, a bad rash all over your body, dizziness, and weakness
 - If you experience a severe allergic reaction, call 9-1-1 or go to the nearest hospital
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- chest pain
- shortness of breath
- feelings of having a fast-beating, fluttering, or pounding heart

- Side effects that have been reported with the vaccine 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; 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

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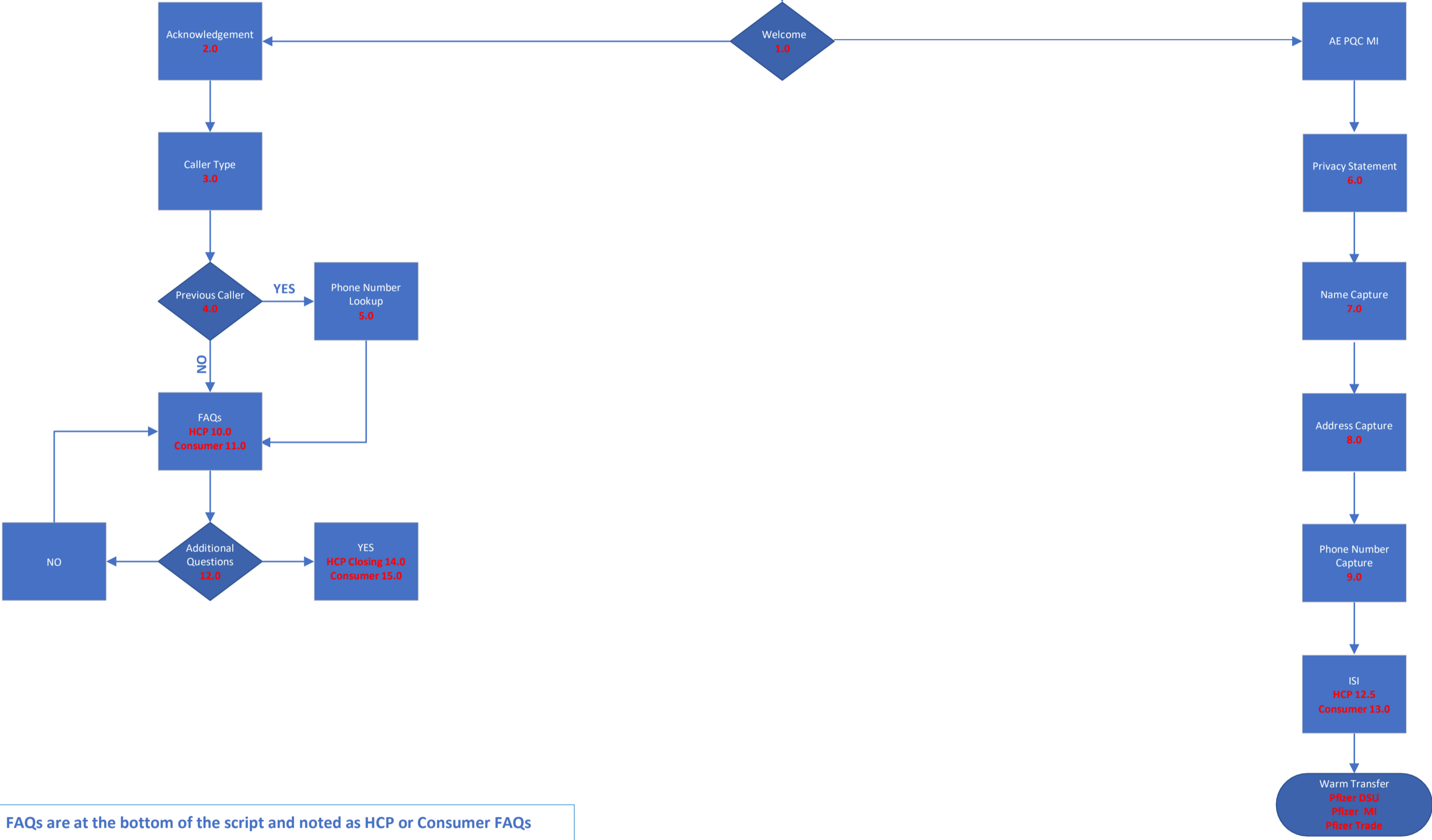
Patients should always ask their healthcare providers for medical advice about adverse events. Report negative side effects of vaccines to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Visit <http://www.vaers.hhs.gov> or call 1-800-822-7967. In addition, you can report side effects to Pfizer Inc. at www.pfizersafetyreporting.com or by calling 1-800-438-1985.

For the most recent 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) please visit www.Comirnaty.com

PP-CVV-USA-0426-02

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Pfizer-BioNTech COVID-19 Vaccine IVR Script
PP-CVV-USA-0303
877-829-2619 (877-VAX-CO19)

Callers come in from:
IVR
Pfizer Trade
First Connect



FAQs are at the bottom of the script and noted as HCP or Consumer FAQs

- HCP FAQs
 - Access
 - Administration
 - Storage and Stability
 - Diluent
 - Dry Ice
 - Shipping Container
 - Additional FAQs
- CONSUMER FAQs
 - Access
 - Additional FAQs

NOTE: Agents will follow directions in FAQs for transfers and reading the ISI where noted.

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 Pfizer-BioNTech COVID-19 Vaccine IVR Script
 PP-CVV-USA-0304
 877-829-2619 (877-VAX-CO19)

877-829-2619 (877-VAX-CO19)
 OR
 Transfer from Pfizer Trade

