UNITED STATES MARINE CORPS
[redacted]

1730
JPH
18 Mar 22

From: Captain Joshua P. Hoppe USMC [redacted]
To: Commanding Officer, Marine [redacted]

Subj: RESPONSE TO ORDER TO RECEIVE COVID-19 VACCINE INOCULATION WITHIN 72 HOURS OF DENIAL OF APPEAL TO COMMANDANT OF THE MARINE CORPS

Ref: (a) The Religious Freedom Restoration Act of 1993
(b) Appeal Denial of Religious Accommodation Request in the Case of Capt Joshua P. Hoppe USMC [redacted]
(c) SECDEF Memo for DoD Mandatory COVID-19 Vaccination 24 Aug 21
(d) MARADMIN 462-21: CMC Mandatory USMC COVID -19 Vaccination 1 Sep 21
(e) 10 U.S. Code § 1107a. Emergency Use Products
(f) FDA Letter of Authorization to Pfizer Reissuing EUA 3 Jan 22
(g) Case No. 3:21-cv-1211-AW-HTC: Order Denying Preliminary Injunction Motions
(h) Memorandum Opinion for Deputy Counsel to the President 6 Jul 21
(i) DoDI 6200.02, Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs 27 Feb 2008
(j) Comirnaty FDA-Approval Letter 23 Aug 21
(k) BUMED Memo for Interchangeability of FDA-Approved Comirnaty and Pfizer-BioNTech EUA 3 Sep 21
(l) ASN M&RA Memo for Pfizer & COMIRNATY 8 Sep 21
(m) ASD Health Affairs Memo for Pfizer & COMIRNATY 4 Sep 21
(n) Fact Sheet for Comirnaty and Pfizer-BioNTech (12yrs) Rev 31 Jan 22

Encl: (1) Order to Receive COVID-19 Vaccine Inoculation within 72 Hours
(2) Photos of Vials Available at BHC MCAS [redacted]
(3) Document #1 sent from Pfizer after Phone Inquiry
(4) Document #2 sent from Pfizer after Phone Inquiry
(5) COVID-19 Vaccine Related Codes Webpage Accessed 16 Mar 22
(6) Pfizer-BioNTech BLA-approved Lots Memo 23 Aug 21
(7) Pfizer-BioNTech 9 Additional Lot Details v3
(8) Expiry Information Document 3 Jan 2022
(9) FDA's Q&A for Comirnaty (COVID-19 Vaccine mRNA) Accessed 17 Mar 22
(10) Email Inquiring About COVID-19 Vaccines and Supply 17 Mar 22

1. The submission of this document serves three purposes:

a. To document my due diligence in acquiring a "COVID-19 inoculation using a Food and Drug Administration (FDA) licensed and approved COVID-19 vaccine," as ordered on 15 Mar 2022 per enclosure (1).

b. To communicate that I do not consent to an injection of any Emergency Use Authorized (EUA) COVID-19 vaccine. Due to my unwavering and sincerely held religious beliefs, if and when an FDA-approved COVID-19 vaccine becomes available I will remain a claimant of reference (a) and all the protections of my religious freedom that it affords.

c. To notify the command of my intent to file a formal Equal Opportunity Complaint for Religious Discrimination in regards to the Assistant Commandant of the Marine Corps' decision on my Religious Accommodation Appeal via the HQMC Inspector General.

Subj: RESPONSE TO ORDER TO RECEIVE COVID-19 VACCINE INOCULATION WITHIN 72 HOURS OF DENIAL OF APPEAL TO COMMANDANT OF THE MARINE CORPS

2. After receiving the email notification of reference (b) on 15 Mar 2022, I received your written order in enclosure (1) on 15 Mar 2022 to receive my first inoculation no later than close of business on 18 Mar 2022 and my second dose by 08 Apr 2022. Your order is written in accordance with the directives given by both the SECDEF and the Commandant, referenced below:

a. SECDEF's 24 August 2021 memorandum; "Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members" [Ref (c)]:

"Mandatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA), in accordance with FDA-approved labeling and guidance."

b. The Commandant's 1 September 2021 MARADMIN 462/21 [Ref (d)]:

"COVID-19 vaccines that have received Food and Drug Administration (FDA) licensure are mandated for all DoD service members by ref (b). FDA Licensed vaccine(s) are the only vaccine(s) that can be mandated for DoD personnel at this time."

3. Between 15 Mar 2022 and the date of this letter, I have exercised due diligence in my attempts to procure a product meeting your order's requirement for a vaccine that is "FDA licensed and approved COVID-19 vaccine." These efforts are summarized as follows:

a. On 16 Mar 2022: I met with the [redacted] Flight Surgeon, LT [redacted], and Mr. [redacted] at the Branch Health Clinic (BHC) MCAS [redacted] to inspect the current inventory of COVID-19 vaccines available at the clinic. The photos in enclosure (2) are the vials of the only vaccines available currently at BHC [redacted] which are labeled "Moderna" and "Pfizer-BioNTech." Both of these vials were clearly marked with the following: "For use under Emergency Use Authorization." Neither were marked as "COMIRNATY" or "SPIKEVAX" which are the only two FDA-Approved and Licensed COVID-19 vaccines to this date. Of note, the "Pfizer-BioNTech" vial inspected was expired as of 12/2021, but Mr. [redacted] stated that they had been given an extension from the FDA. When asked for a Fact Sheet for the vaccines currently in stock, I was told that they did not have any paper copies on hand, so LT [redacted] emailed me PDF copies later for my reference as well as the confirmation of when or if the clinic would be getting the FDA-approved vaccines. They both told me that they believed these vials were part of the approved lot numbers that were BLA-approved (paragraph 3.d. demonstrates the contrary).

b. On 16 Mar 2022: I called Walgreens at [redacted] Ave, a civilian pharmacy within the local area, and spoke with [redacted]. I was able to confirm with [redacted] that the only product they had on hand labeled "Pfizer-BioNTech" which also stated "For use under Emergency Use Authorization." Of note, when asked to check for the EUA labeling, the pharmacist questioned "Emergency" and stated that he had never heard of the vaccines being labeled for "Emergency Use" before, he had never checked the vial label before, and recollected that he was told these were the ones that they were cleared to give out. The reason I note this is because I believe the medical providers are not being appropriately made aware of the true nature of EUA products and the rights that ALL individuals are entitled to absent a presidential waiver of informed consent in accordance with reference (e) (i.e. informed of an option to accept or refuse administration of a product under EUA).

c. On 16 Mar 2022: I called Pfizer to ask if any of the FDA-approved and properly labeled "Comirnaty" vaccines were available anywhere in the United States. Speaking directly with [redacted] at 1-800-438-1985 (opt 3, opt

"Comirnaty", opt 2, waited online for representative) he confirmed that Pfizer's FDA-approved "Comirnaty" vaccine is not available anywhere in the United States, nor will Pfizer begin producing "Comirnaty" until the EUA products are no longer in use (no timeframe was given). While on hold with Pfizer, there was a recording that stated that Pfizer could give "no specific information for when Comirnaty would become available." I also asked for clarification on what the "interchangeability" yet "legally distinct" means in regards to the EUA and FDA-approved products (i.e. Pfizer-BioNTech and Comirnaty). [redacted] explained that the manufacturing process and labeling as required in the FDA approval and BLA licensing is what makes the legal distinction.

(1) [redacted] sent me enclosure (3) in response to my inquiry about Comirnaty and the "interchangeability" yet "legally distinct". Enclosure (3) reiterated the interchangeability of the FDA approved Comirnaty with the EUA Pfizer-BioNTech, but it did not mention or expound on the clarification of legally distinct.

(2) [redacted] also sent me enclosure (4) in response to the question if Comirnaty was available anywhere in the United States. The answer provided was: "During an Emergency Use Authorization (EUA), Pfizer does not have the ability to provide this vaccine to you." Furthermore, both enclosures provided the advisory: "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." Once the conditions are no longer met the EUA is no longer valid.

d. On 16 Mar 2022: I checked the CDC's COVID-19 Vaccine Related Codes Webpage (https://www.cdc.gov/vaccines/programs/iis/COVID-19-related-codes.html) as captured in enclosure (5). On page 5 of enclosure (5) it states: "The following vaccines and associated tradenames have been approved by the FDA under BLA License. They are listed separately because while they may represent the same formulations as the EUA authorized and labeled products listed above, the NDCs listed with the new BLA licensed tradenames in the FDA BLA approval or the FDA Structured Product Labels (SPL) are not currently being produced by the manufacturers while EUA product is available" (emphasis added). Pages 5 and 6 list COMIRNATY and SPIKEVAX as the only BLA-licensed products and list the various approved National Drug Codes (NDCs) which are not consistent with the vials shown in enclosure (2). Furthermore, all BLA-licensed products state: "**At present, Pfizer does not plan to produce any product with these new NDCs and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution.** As such, the CDC, AMA, and drug compendia may not publish [or may delay publishing] these new codes until Pfizer [or Moderna] has determined when the product will be produced with the BLA labels" (emphasis added).

e. On 17 Mar 2022: I accessed https://www.cvdvaccine-us.com/16-up-yearsold/resources and downloaded enclosures (6) and (7) under "Resources to support you and your staff" and in the drop-link "Important Lot Information." Enclosure (8) was under "Storage, Shipping, and Handling Resources" in the drop-link "Expiry Information."

(1) Enclosure (6) was released the same day as reference (j) and provides the guidance for "**Certain Pfizer-BioNTech COVID-19 Vaccine Lots authorized for Emergency Use comply with the Biologics License Application (BLA).**" It states that: "**Some of these lots comply with the recently approved**

**BLA for COMIRNATY and are therefore considered "BLA-approved" lots for administration to individuals 16 years of age and older."**

(2) Enclosure (7) can also be accessed by scanning the QR code on enclosure (6) and provides the 9 additional lot details for the BLA-approved Pfizer-BioNTech COVID-19 vaccines. None of these 9 lot numbers were in stock at any pharmacy that I checked with.

(3) Enclosure (8) lists the updated expiration dates of the Pfizer vaccines that was released when the EUA was reissued in reference (f). There was no guidance in this document as to if the expiration was on the first or last day of the month that the vials expired. When I called Pfizer again on 17 March 2022, [redacted] told me that it was the last day of the month but did not have any document he could send me to verify this.

f. On 17 Mar 2022: I called Pfizer and spoke to [redacted] again after using the same prompts. This time I asked about expiration dates (addressed), the ability to check the system for specific lot numbers in search of a BLA-approved Pfizer vaccine, and inquire if there was anything else he could send with amplifying information on the "legally distinct" verbiage that is still present in the most recent EUA of reference (f). [redacted] informed me that Pfizer did not have the ability to check for individual lot numbers currently in circulation or their locations. He told me to try and contact my physician for that specific request. [redacted] reiterated the same explanation about the legal distinction, but did not have anything else he could send to explain further.

g. On 17 Mar 2022: I called CVS Pharmacy at [redacted] Pkwy, a civilian pharmacy within the local area. The pharmacist I spoke with confirmed that the only COVID-19 vaccine they had on hand was Pfizer-BioNTech. When asked if it had "Emergency Use Authorization" on the label, she did not understand what I was asking for and told me that they were good for anyone to receive who were 12 years old and up. When I asked her to check the lot numbers, she gave me the last three digits which did not match any of the 9 BLA-approved lots. When I asked her what other writing was on the label, she told me there was no other writing and it only had "Pfizer-BioNTech COVID-19 Vaccine" written on the vial. I then asked her what color cap was on it and she told me it was "grey." I found it odd that there was no other markings on the vial and the fact that the lady who told me she was the actual pharmacist for the pharmacy had no knowledge about the differences between the EUA and FDA-approved products. I then asked her if they give out Fact Sheets when someone receives a vaccine and she informed me that they do when the person asks for it. I could be wrong, but I thought this was a requirement for when someone receives a COVID-19 vaccine.

h. On 17 Mar 2022: I called and spoke with LCDR [redacted], the OIC of NMRTU [redacted] to ask about the capability to check the system for specific lot numbers to see if he could locate a BLA-approved and compliant Pfizer-BioNTech vaccine. He explained to me that they do not get to choose which vaccines are purchased. They will submit an order for the amount they would like to purchase and it gets filled with whatever is currently available. He said he could forward the lot numbers to their supplier in Camp [redacted] though to see if they could check, so I sent him a copy of enclosures (6) through (8) via email. I am still pending the response of the inquiry as documented in enclosure (10).

4. I acknowledge the existence of opinions regarding the interchangeability of the EUA products with the FDA-approved products. Per the FDA's own language, however, the FDA-approved products and EUA products remain "legally

distinct" [Ref (f), page 12, para 3, sent 3]. The various medical interchangeability opinions and DoD guidance are not authoritative on the subject and do not override federal law found in reference (e). As such, the EUA products cannot be substituted for the purposes of the mandate nor to fulfill your 15 Mar 2022 order for me to receive a vaccine with "FDA licensed and approved COVID-19 vaccine."

a. This has been verified in the Federal District Court by Judge Allen Winsor when he rejected the DoD's claim by stating in reference (g) on page 14: "The DOD's interpretation of § 1107a is unconvincing. For starters, FDA licensure does not retroactively apply to vials shipped before BLA approval. See 21 U.S.C. § 355(a) ("No person shall introduce . . . into interstate commerce any new drug, unless an approval of an application [for FDA licensure] is effective with respect to such drug." (emphasis added)). Thus, as a legal matter, vaccines sent before August 23—and vaccines produced after August 23 in unapproved facilities—remain "product[s] authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act." § 1107a(a)(1).9 Section 1107a's explicit cross-reference to the EUA provisions suggests a concern that drugs mandated for military personnel be actually BLA-approved, not merely chemically similar to a BLA-approved drug."

b. Also noted in reference (f) is the fact that Pfizer's EUA for Pfizer-BioNTech has been reissued 8 times since FDA approved the Comirnaty product. On page 2 it states: "On August 23, 2021, FDA approved COMIRNATY (COVID-19 Vaccine, mRNA and reissued the letter in its entirety for both Pfizer-BioNTech COVID-19 Vaccine and certain uses of COMIRNATY (COVID-19 Vaccine, mRNA)." Subsequently, the FDA reissued the letter of authorization (LOA) on September 22, 2021; October 20, 2021; October 29, 2021; November 19, 2021; December 9, 2021; December 16, 2021; and most recently on January 3, 2022. The reason the EUA LOA met the criteria for reissuance is stated on page 10, para I.C: "There is no adequate, **approved**, and available alternative Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19" (emphasis added). Meaning once an FDA approved COVID-19 is available in the market all the EUA products will expire and no longer able to be used.

c. I note that the Navy and DoD's guidance issued in references (k) through (m) all quote the interchangeability from the EUAs, but they all woefully fail to mention or attempt to explain the "legally distinct" verbiage found in the EUAs usually following the interchangeable sentence. I also note, that these references are all dated after reference (c).

(1) Reference (k) states that the EUA was "revised" on the same day that Comirnaty was approved. This is not factually accurate and is misleading. The FDA "reissued the letter in its entirety" as noted in reference (f). Reference (k) concludes that the EUA vaccines can be used for mandatory vaccinations contrary to references (e), (h), and (i) and without mentioning the "legally distinct" verbiage in reference (f).

(2) Reference (l) quotes the FDA's guidance on the EUA and licensed Comirnaty vaccines as having "the same formulation and are interchangeable." The memo then references the Surgeon General's memo in reference (k) for amplifying guidance. Reference (l) concludes again that the EUA vaccines can be used for mandatory vaccinations contrary to references (e), (h), and (i) and without mentioning the "legally distinct" verbiage in reference (f).

(3) Reference (m) again defers to the FDA's guidance for the EUA and FDA-approved to be "interchangeable," and quotes the FDA's webpage "Q&A for Comirnaty (COVID-19 Vaccine mRNA)," accessed on September 10, 2021. That webpage is included as enclosure (9) for reference as accessed on March 17,

2022. The webpage then references the Fact Sheet [Ref (n)] for "additional information about both the approved and authorized vaccines." Of note, neither enclosure (9) or reference (n) site the "legally distinct" despite the most recent EUA [Ref (f)] citing the distinction. Reference (m) concludes again that the EUA vaccines can be used for mandatory vaccinations contrary to references (e), (h), and (i) and without mentioning the "legally distinct" verbiage in reference (f).

5. The specific language consistently stated in the orders received thus far recognize that absent a written waiver from the President of the United States, the only vaccine that can be currently mandated to service members are those that are fully licensed and approved by the FDA. The President has not granted this written waiver.

a. Reference (h) states on page 16: "Consistent with this legislative history and the vesting of the waiver authority in the President, DOD informs us that it has understood section 1107a to mean that DOD may not require service members to take an EUA product that is subject to the condition regarding the option to refuse, unless the President exercises the waiver authority contained in section 1107a."

b. Reference (i) states in paragraph E3.4: "In the event that an EUA granted by the Commissioner of Food and Drugs includes a condition that potential recipients are provided an option to refuse administration of the product, the President may, pursuant to section 1107a of Reference (e), waive the option to refuse for administration of the medical product to members of the armed forces. Such a waiver is allowed if the President determines, in writing, that providing to members of the armed forces an option to refuse is not in the interests of national security. Only the Secretary of Defense may ask the President to grant a waiver of an option to refuse."

6. In summary, I have documented my due diligence to locate a "COVID-19 inoculation using a Food and Drug Administration (FDA) licensed and approved COVID-19 vaccine," and demonstrated that are no FDA-approved or BLA-approved vaccines available to make the order legally enforceable. I do not consent to an injection of any Emergency Use Authorized (EUA) product. Due to my unwavering and sincerely held religious beliefs, if and when an FDA-approved COVID-19 vaccine becomes available I will remain a claimant of reference (a) and all the protections of my religious freedom that it affords. I now intend to file a formal Equal Opportunity Complaint for Religious Discrimination in regards to the Assistant Commandant of the Marine Corps' decision on my Religious Accommodation Appeal via the HQMC Inspector General.

7. The point of contact for this matter is Captain Joshua P. Hoppe who can be reached at commercial: [redacted] or email: [redacted]@usmc.mil.

J. P. HOPPE

UNITED STATES MARINE CORPS

[redacted]

5800
CO
15 MAR 2022

From: Commanding Officer, [redacted]
To: Captain Joshua P. Hoppe [redacted] USMC

Subj: ORDER TO RECEIVE COVID-19 VACCINE INOCULATION WITHIN 72 HOURS OF DENIAL OF APPEAL TO ASSISTANT COMMANDANT OF THE MARINE CORPS

Ref: (a) ACMC ltr to Capt Hoppe of 14 Mar 22
(b) MARADMIN 612/21

1. Reference (a) denies your appeal to the Assistant Commandant of the Marine Corps requesting for religious accommodation exempting you from inoculation for COVID-19. In accordance with reference (b), you are hereby ordered to submit to inoculation for COVID-19 within 72 hours of this Order, specifically through receipt of a COVID-19 inoculation using a U.S. Food and Drug Administration (FDA) licensed and approved COVID-19 vaccine. If you voluntarily receive a complete series of an FDA Emergency Use Authorization COVID-19 vaccine, or a vaccine included in the World Health Organization Emergency Use Listing, these vaccination series will satisfy the inoculation requirement of this Order.

2. Your new inoculation deadlines are as follows:

First Dose: 18 MAR 2022

Second Dose: 08 APR 2022

3. If you fail to meet the inoculation deadlines stated above you will be in violation of this Order. Pursuant to reference (b), you will be reported to Headquarters Marine Corps for entry into the Officer Disciplinary Notebook. You will also be subject to the appropriate administrative or disciplinary action.

4. If you cannot secure the vaccination due to vaccine shortages, document each attempt made to secure the vaccine with the assistance of your chain of command, and submit the account to me before the 10th calendar day on which your vaccination or exemption request is due.

[redacted]

Enclosure (1)

JPH
15 MAR 2022

FIRST ENDORSEMENT

From: Captain Joshua P. Hoppe [redacted] USMC
To: Commanding Officer, [redacted]

Subj: ORDER TO RECEIVE COVID-19 VACCINE INOCULATION WITHIN 72 HOURS OF DENIAL OF APPEAL TO ASSISTANT COMMANDANT OF THE MARINE CORPS

1. I have read and understand this Order, and am aware of my responsibility to receive the COVID-19 vaccine inoculation within 72 hours of the date of this Order, and receive the second inoculation as stated in paragraph 2. I acknowledge that failure to comply with this Order and submit to the COVID-19 inoculation as stated in paragraph 2, will result in a report to Headquarters Marine Corps and entry of my name on the Officer Disciplinary Notebook. I also understand that I will be subject to the appropriate administrative or disciplinary action.

J. P. HOPPE

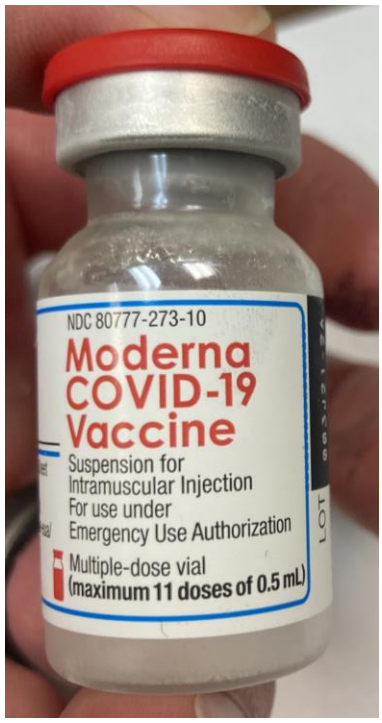


Enclosure (1)

## Photos of Available COVID-19 Vaccines at BHC MCA [redacted]

Pfizer-BioNTech COVID-19 Vaccine Vials


Moderna COVID-19 Vaccine Vials






16-March-2022

ppe
gmail.com

Dear Joshua Hoppe,

Thank you for your inquiry about COMIRNATY (COVID19 Vaccine, mRNA).

There are 3 authorized presentations of Pfizer-BioNTech COVID-19 Vaccine. Each has specific age authorizations, storage, handling, and preparation requirements.
(1) Formulation for individuals 12 years and older (DILUTE BEFORE USE/purple cap);
(2) Formulation for individuals 12 years and older (DO NOT DILUTE/gray cap); and
(3) Formulation for individuals 5 through 11 years (DILUTE BEFORE USE/orange cap).

The U.S. Food and Drug Administration (FDA)-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the two Emergency Use Authorization (EUA) authorized formulations of Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older, when prepared according to their respective instructions for use, 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.

COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine that is indicated for active immunization to prevent COVID-19 in individuals 16 years of age and older. It is approved for use as a 2-dose primary series for the prevention of COVID-19 in individuals 16 years of age and older. It is also authorized for emergency use to provide a 2-dose primary series to individuals 12 through 15 years.

Pfizer-BioNTech COVID-19 Vaccine (purple or gray cap) is authorized for use to provide a 2-dose primary series to individuals 12 years of age and older.

COMIRNATY and the Pfizer-BioNTech COVID-19 Vaccine (purple or gray cap) are authorized for use under an EUA from FDA to provide a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise and as a single booster dose to individuals 12 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY. The vaccines are also authorized as a single booster dose to individuals 18 years of age and older who have completed primary vaccination with another authorized or approved COVID-19 vaccine. The booster schedule is based on the labeling information of the vaccine used for the primary series.

Pfizer-BioNTech COVID-19 Vaccine (orange cap) is authorized for use to provide a 2-dose primary series to individuals 5 through 11 years of age. The vaccine is also authorized to provide a third primary series dose to individuals 5 through 11 years of age who have been determined to have certain kinds of immunocompromise.

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.

***Vaccine Recipients and Caregivers***: please refer to the age-appropriate Vaccine Information Fact Sheet for Recipients and Caregivers on important treatment considerations for COMIRNATY and the Pfizer-BioNTech COVID-19 Vaccine via the following link: https://www.pfizermedicalinformation.com/en-us/patient/pfizer-biontech-covid-19-vaccine. In the event this link does not work, please access the product's Fact Sheet or Prescribing Information at www.pfizer.com.

***Healthcare Providers***: please refer to the full COMIRNATY Prescribing Information for individuals 16 years of age and older for important treatment considerations for COMIRNATY via the following link: (https://www.pfizermedicalinformation.com/en-us/pfizer-biontech-covid-19-vaccine) or www.cvdvaccine.com. Please refer to the appropriate Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 including Full EUA Prescribing Information on important treatment considerations for the Pfizer-BioNTech COVID-19 Vaccine via the following link: https://www.pfizermedicalinformation.com/en-us/patient/pfizer-biontech-covid-19-vaccine or www.cvdvaccine.com.

*If you did not specifically request this information, please call 1-800-438-1985 to report this to us.*

The product prescribing information can be accessed on www.pfizer.com. The website www.pfizermedinfo.com offers a patient portal where patients or caregivers can access information about Pfizer prescription products as well other patient health resources.

Thank you for your interest in Pfizer. To reach Pfizer Medical Information or to report a suspected adverse event or concern about the quality of a Pfizer product, please call 1-800-438-1985.

Sincerely,
Pfizer Medical Information

00600861

Enclosures:
CONS-how can I get access to covid-19 vaccine during EUA and after FDA approval?
CONS-how can I get access to covid-19 vaccine during EUA and after FDA approval?

**Disclaimers**

This information is supplied as a professional courtesy in response to your inquiry. It is intended to provide pertinent data to assist you in forming your own conclusions and making decisions. The information is not intended to advocate any indication, dosage or other claim that is not covered in the product prescribing information, which can be accessed on www.pfizer.com or by contacting us.

Pfizer Medical Information collects your personal information to address or provide a response to your medical inquiry. We may share this information with other Pfizer colleagues to ensure that your inquiry is addressed appropriately. Any information you choose to provide Pfizer is entirely voluntary. Please note we may be limited in our ability to respond to your inquiry or to honor your preference in method of communication if you choose not to provide certain personal information. If you report an adverse event or concern about the quality of a Pfizer product, we will need to use the information that you have given us in order to meet our regulatory requirements in relation to the safety of our medicines. It may be necessary for us to share your information with Pfizer's affiliates, partners and regulatory authorities located in countries besides your own. Pfizer has implemented measures to protect the personal information you provide. For additional information about the handling of your personal information, please visit Pfizer.com/Privacy and to exercise any rights requests related to your personal information, please complete the request at Pfizer.com/individualrights and we will respond in accordance with local law.

**Comirnaty (koe-mir'-na-tee), COVID-19 Vaccine, mRNA**

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the two formulations of Pfizer-BioNTech COVID-19 Vaccine authorized for Emergency Use Authorization (EUA) for ages 12 years and older, when prepared according to their respective instructions for use, can be used interchangeably without presenting any safety or effectiveness concerns.

Comirnaty is FDA-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 a two-dose primary series in individuals 12 through 15 years. 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 and to provide a two-dose primary series to individuals 5 through 11 years of age. Comirnaty and the Pfizer-BioNTech COVID-19 Vaccine have received EUA from FDA to provide a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise and as a single booster dose in individuals 16 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY. The vaccines are also authorized as a single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine. The booster schedule is based on the labeling information of the vaccine used for the primary series. 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.

---

## QUESTION: HOW CAN I GET ACCESS TO THE VACCINE DURING THE EMERGENCY USE AUTHORIZATION (EUA) and AFTER FDA APPROVAL?

---

## ANSWER:

During an Emergency Use Authorization (EUA), Pfizer does not have the ability to provide this vaccine to you. Each state has its own plan for deciding which groups of people will be vaccinated and where you can get vaccinated.

You can contact your state health department for more information on its COVID-19 vaccination plan.

You can also find helpful information on the U.S. Centers for Disease Control and Prevention (CDC) website. The CDC website has information to help you find a vaccination site near you.

Here is a link for this information from the CDC:
www.cdc.gov/coronavirus/2019-ncov/vaccines/How-Do-I-Get-a-COVID-19-Vaccine.html

After FDA approval, until further notice, the government will continue to determine where the vaccine is shipped and made available.

At this time, people will continue to be vaccinated at the same sites set up during EUA – depending on location, this may include mass vaccination sites established by the state or county, pharmacies or drugstores, doctors' offices and other healthcare centers. The U.S. government can also decide to make changes as needed.

***Learn More:***

### What can I do with this information?

This document provides an answer to your question about a Pfizer product but it does not contain all the available information. It does not take the place of talking to your vaccination provider, doctor, or pharmacist. This information is provided for informational purposes only and is not meant to be a substitute for advice provided by a vaccination provider, doctor, or other qualified health care professional. Patients should not use this information for diagnosing a health or fitness problem or disease. You should always talk with a vaccination provider, doctor, or other qualified health care professional about whether a specific treatment or medication is right for you and before starting a new treatment or activity. They are in the best position to advise you about the suitability of a particular treatment as they have access to the details of your medical history, as well as to information on all medical products.

### Where can I get more information?

Please refer to the Vaccine Information Fact Sheet for Recipients and Caregivers about Comirnaty (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) on important treatment considerations for Comirnaty and the Pfizer-BioNTech COVID-19 Vaccine via the following link: https://www.pfizermedicalinformation.com/en-us/patient/pfizer-biontech-covid-19-vaccine or www.cvdvaccine.com. In the event this link does not work, please access the product's Fact Sheet or Prescribing Information at www.pfizer.com.

Centers for Disease Control and Prevention

# COVID-19 Vaccine Related Codes

## COVID-19 Vaccine Codes

### Preview Posting of COVID-19 Vaccine Codes and Crosswalk for Currently Authorized Vaccines and Anticipation of Potential Vaccine Availability under Emergency Use Authorization (EUA)

*Note: Codes will become effective only upon EUA issuance or BLA licensure of COVID-19 vaccine(s) by the Food and Drug Administration (FDA)*

The codes and crosswalk for candidate COVID-19 vaccines will be posted for preview in phases as the late-stage clinical trials for candidate vaccines progress. Additional vaccines or codes will be added to this list as they enter late-stage clinical trials or prepare applications for FDA authorization.

The following downloadable table provides a summary of the currently authorized vaccine codes and a preview of the vaccine codes that will be activated if the FDA authorizes use and ACIP votes to recommend the candidate vaccines.

To support this effort, the CDC is working closely with data partners responsible for the creation and distribution of vaccine codes and drug compendia publishers to coordinate the release of codes in advance of potential EUAs to enable systems and users that require these codes to prepare in advance.

The codes for these vaccines are also included in the vaccine code set files unless otherwise noted in the table. Additional code details and fields values are included in the vaccine code sets.

American Medical Association (AMA) COVID-19 CPT® vaccine product and administration codes are now available on the AMA web site. The CPT vaccine product codes are included in the Preview COVID-19 table and the CDC vaccine code sets. You can access further information regarding the COVID-19 CPT codes, as well as the associated coding guidance, using the following link:

https://www.ama-assn.org/practice-management/cpt/covid-19-cpt-vaccine-and-immunization-codes

Download the Preview Table *for US vaccine administration only*: Excel Version

COVID-19 vaccine codes and crosswalks are provided in anticipation of potential vaccine availability under an approved Biologics License Application (BLA), Emergency Use Authorization (EUA), or as a potential vaccine submission for EUA (Pre-EUA) as of 02/14/2022. Codes will become effective for US vaccine administrations only upon EUA issuance and/or BLA approval of COVID-19 vaccine(s) by the FDA. All CVX codes are associated to the new Vaccine Group “COVID-19.” CPT Codes shown are product codes. CPT administrative codes for doses are available on the AMA website. CPT product codes are added as the AMA approves and makes them available.

| Manufacturer | FDA Authorization (BLA, EUA, Pre-EUA) | Sale Proprietary Name | Product Description | Unit of Sale NDC10 (UOS) | UoS Package | Unit of Use NDC10 (UOU) | UoU Presentation | CVX Code | CVX Long Description | CVX Short Description |
|---|---|---|---|---|---|---|---|---|---|---|

Enclosure (5)

| Manufacturer | FDA Authorization (BLA, EUA, Pre-EUA) | Sale Proprietary Name | Product Description | Unit of Sale NDC10 (UOS) | UoS Package | Unit of Use NDC10 (UOU) | UoU Presentation | CVX Code | CVX Long Description | CVX Short Description |
|---|---|---|---|---|---|---|---|---|---|---|
| Janssen Products, LP | EUA-authorized (18+) | Janssen COVID-19 Vaccine (BLUE CAP) | 5×10^10 viral particles/0.5 mL for adult 18+ | 59676-580-15 | CARTON, 10 MULTI-DOSE VIALS | 59676-580-05 | VIAL, MULTI-DOSE | 212 | SARS-COV-2 (COVID-19) vaccine, vector non-replicating, recombinant spike protein-Ad26, preservative free, 0.5 mL | COVID-19 vaccine, vector-nr, rS-Ad26, PF, 0.5 mL |
| Moderna US, Inc. | EUA-authorized (18+) | Moderna COVID-19 Vaccine (RED CAP) | 100 mcg/0.5 mL for adult 18+ (existing product) | 80777-273-99 | CARTON, 10 MULTI-DOSE VIAL 5 mL EACH | 80777-273-10 | VIAL, 5 mL, MULTI-DOSE VIAL | 207 | SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 100 mcg/0.5mL dose or 50 mcg/0.25mL dose | COVID-19, mRNA, LNP-S, PF, 100 mcg/0.5mL dose or 50 mcg/0.25mL dos |
| | | | | 80777-273-98 | CARTON, 10 MULTI-DOSE VIAL 7 mL EACH | 80777-273-15 | VIAL, 7 mL, MULTI-DOSE VIAL | | | |
| Moderna US, Inc. | EUA-authorized (18+) | Moderna COVID-19 Vaccine (RED CAP) | 50 mcg/0.25 mL for booster adult 18+ (existing product), drawn from same vial as primary series | 80777-273-99 | CARTON, 10 MULTI-DOSE VIAL 5 mL EACH | 80777-273-10 | VIAL, 5 mL, MULTI-DOSE VIAL | 207 | SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 100 mcg/0.5mL dose or 50 mcg/0.25mL dose | COVID-19, mRNA, LNP-S, PF, 100 mcg/0.5mL dose or 50 mcg/0.25mL dos |
| | | | | 80777-273-98 | CARTON, 10 MULTI-DOSE VIAL 7 mL EACH | 80777-273-15 | VIAL, 7 mL, MULTI-DOSE VIAL | | | |

Enclosure (5)

| Manufacturer | Pre-EUA Authorization (BLA, EUA, Pre-EUA) | Proprietary Name | Product Description | Sale Unit of Use NDC10 (UOS) | Sale Package | Use Unit of Use NDC10 (UOU) | Use Presentation | CVX Code | CVX Long Description | CVX Short Description |
|---|---|---|---|---|---|---|---|---|---|---|
| Moderna US, Inc. | EUA | Moderna COVID-19 Vaccine (DARK BLUE CAP) | 50 mcg/0.50 mL for adult concentration | 80777-273-99 | CARTON, 10 MULTI-DOSE VIAL 2.5 mL EACH | 80777-273-05 | VIAL, 2.5 mL, MULTI-DOSE VIAL | 221 | SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 50 mcg/0.5 mL dose | COVID-19, mRNA, LNP-S, PF, 50 mcg/0.5 mL dose |
| Pfizer-BioNTech | EUA-authorized for ages 12 yrs + | Pfizer-BioNTech COVID-19 Vaccine (PURPLE CAP) (Original product formulation) | 30 mcg/0.3 mL for primary series, IC 3rd dose, booster | 59267-1000-2 | CARTON, 195 MULTI-DOSE VIALS | 59267-1000-1 | MULTI-DOSE VIAL | 208 | SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 30 mcg/0.3 mL dose | COVID-19, mRNA, LNP-S, PF, 30 mcg/0.3 mL dose |
| | | | | 59267-1000-3 | CARTON, 25 MULTI-DOSE VIALS | | | | | |
| Pfizer-BioNTech | EUA-authorized for ages 12 yrs + Note: BLA-licensed for (16+) | Pfizer-BioNTech COVID-19 Vaccine (GRAY CAP) (Tris-sucrose formulation) | 30 mcg/0.3 mL for primary series, IC 3rd dose, booster | 59267-1025-3 | CARTON, 25 MULTI-DOSE VIALS | 59267-1025-1 | VIAL, 2.25 mL, MULTI-DOSE VIAL | 217 | SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 30 mcg/0.3 mL dose | COVID-19, mRNA, LNP-S, PF, 30 mcg/0.3 mL dose |
| | | | | 59267-1025-4 | CARTON, 10 MULTI-DOSE VIALS | | | | | |
| Pfizer-BioNTech | EUA-authorized for ages 5 yrs to < 12 yrs | Pfizer-BioNTech COVID-19 Vaccine (ORANGE CAP) (Tris-sucrose | 10 mcg/0.2 mL for primary series, IC 3rd dose | 59267-1055-4 | CARTON, 10 MULTI-DOSE VIALS | 59267-1055-1 | VIAL, 2 mL, MULTI-DOSE VIAL | 218 | SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 10 mcg/0.2 mL dose, tris-sucrose formulation | COVID-19, mRNA, LNP-S, PF, 10 mcg/0.2 mL dose, tris-sucrose |

Enclosure (5)

| Manufacturer | FDA Authorization (BLA, EUA, Pre-EUA) | formulation) Sale Proprietary Name | Product Description | Unit of Sale NDC10 (UOS) | UoS Package | Unit of Use NDC10 (UOU) | UoU Presentation | CVX Code | CVX Long Description | CVX Short Description |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | |
| Pfizer-BioNTech | Pre-EUA for ages 6 mo to <5 yrs | Pfizer-BioNTech COVID-19 Vaccine (MAROON CAP)<br><br>(Tris-sucrose formulation) | 3 mcg/0.2 mL for primary series | 59267-0078-4 | CARTON, 10 MULTI-DOSE VIALS | 59267-0078-1 | VIAL, 2 mL, MULTI-DOSE VIAL | 219 | SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 3 mcg/0.2 mL dose, tris-sucrose formulation | COVID-19, mRNA, LNP-S, PF, 3 mcg/0.2 mL dose, tris-sucrose |
| | | | | | | | | | | |
| Novavax, Inc. | Pre-EUA | Novavax COVID-19 Vaccine | 5 mcg/0.5 mL, primary series, adult | 80631-100-10 | CARTON, 10 VIAL, MULTI-DOSE | 80631-100-01 | VIAL, MULTI-DOSE, 5 mL | 211 | SARS-COV-2 (COVID-19) vaccine, Subunit, recombinant spike protein-nanoparticle+Matrix-M1 Adjuvant, preservative free, 0.5mL per dose | COVID-19 vaccine, Subunit, rS-nanoparticle+Matrix-M1 Adjuvant, PF, 0.5 mL |
| | | | | | | | | | | |
| Sanofi Pasteur | Pre-EUA Authorization | Sanofi Pasteur COVID-19 Vaccine, primary series, adult | 10mcg/0.5mL dose, including added AS03 adjuvant, primary series | No production planned for adult series vaccine in U.S. market at this time | | | | 226 | SARS-COV-2 (COVID-19) vaccine, D614, prefusion spike recombinant protein subunit (CoV2 preS dTM), AS03 adjuvant added, preservative free, 10mcg/0.5mL dose | COVID-19, D614, recomb, preS dTM, AS03 adjuvant add, PF, 10mcg/0.5mL |

Enclosure (5)

| Manufacturer | FDA Authorization (BLA, EUA, Pre-EUA) | Sale Proprietary Name | Product Description | Unit of Sale NDC10 (UOS) | UoS Package | Unit of Use NDC10 (UOU) | UoU Presentation | CVX Code | CVX Long Description | CVX Short Description |
|---|---|---|---|---|---|---|---|---|---|---|
| Sanofi Pasteur | Pre-EUA | Sanofi Pasteur COVID-19 Vaccine booster dose, adult | 5mcg/0.5mL dose, Preservative free, adjuvant, booster dose | 49281-420-10 | 10 MULTI-DOSE ANTIGEN ONLY | 49281-078-10 | VIAL, MULTI-DOSE, ANTIGEN | 225 | SARS-COV-2 (COVID-19) vaccine, D614, recombinant spike protein-nanoparticle subunit (CoV2 preS dTM), AS03 adjuvant added, preservative free, 5mcg/0.5mL dose | COVID-19, D614, recomb, preS dTM, AS03 adjuvant add, PF, 5mcg/0.5mL |
| AstraZeneca Pharmaceuticals LP | Pre-EUA | AstraZeneca COVID-19 Vaccine | 5×10^10 viral particles/0.5 mL, adult | No active NDC codes for U.S. Market | | | | 210 | SARS-COV-2 (COVID-19) vaccine, vector non-replicating, recombinant spike protein-ChAdOx1, preservative free, 0.5 mL | COVID-19 vaccine, vector-nr, rS-ChAdOx1, PF, 0.5 m |

Unspecified US COVID-19 Vaccine CVX Code

| CVX Short Description | CVX Code | CVX Long Description | Note | Vaccine Status |
|---|---|---|---|---|
| SARS-COV-2 (COVID-19) vaccine, UNSPECIFIED | 213 | SARS-COV-2 (COVID-19) vaccine, UNSPECIFIED | Unspecified code for COVID-19 not to be used to record patient US administration. May be used to record historic US administration if product is not known. CVX code 500 should be used to record Non-US vaccine where product is not known. | Inactive |

The following vaccines and associated tradenames have been approved by the FDA under BLA License. They are listed separately because while they may represent the same formulations as the EUA authorized and labeled products listed above, the NDCs listed with the new BLA licensed tradenames in the FDA BLA approval or the FDA Structured Product Labels (SPL) are not currently being produced by the manufacturers while EUA product is available.

| Manufacturer | FDA Authorization (BLA, EUA, Pre-EUA) | Sale Proprietary Name | Product Description | Unit of Sale NDC10 (UOS) | UoS Package | Unit of Use NDC10 (UOU) | UoU Presentation | |
|---|---|---|---|---|---|---|---|---|
| Pfizer-BioNTech | BLA-licensed for ages 16+ | COMIRNATY | 30 mcg/0.3 mL for adult 16+ (original formula) | 0069-1000-02 | CARTON, 195 MULTI-DOSE VIALS | 0069-1000-01 | VIAL, 2 mL, MULTI-DOSE VIAL | COMINARTY products are not orderable at this time. NDCs are listed per FDA Structured Product Label (SPL) document for the BLA licensed product. These codes are not included in CDC Vaccine Code Set files at this time. Pfizer has provided the following statement regarding the COMINARTY branded NDCs and labels: "Pfizer received FDA BLA license on 8/23/2021 for its COVID-19 vaccine for use in individuals 16 and older (COMIRNATY). At that time, the FDA published a BLA package insert that included the approved new COVID-19 vaccine tradename |
| | | | | 00069-1000-03 | CARTON, 25 MULTI-DOSE VIALS | | | |
| Pfizer-BioNTech | BLA-licensed for ages 16+ | COMIRNATY | 30 mcg/0.3 mL for adult 16+ (Same as EUA tris sucrose formula) | 0069-2025-10 | CARTON, 10 MULTI-DOSE VIALS | 0069-2025-01 | VIAL, 2 mL, MULTI-DOSE VIAL | |

Enclosure (5)

| Manufacturer | FDA Authorization (BLA, EUA, Pre-EUA) | Sale Proprietary Name | Product Description | Unit of Sale NDC10 (UOS) | UoS Package | Unit of Use NDC10 (UOU) | UoU Presentation | |
|---|---|---|---|---|---|---|---|---|
| | | | | 0069-2025-25 | CARTON, 25 MULTI-DOSE VIALS | | | COMIRNATY and listed 2 new NDCs (0069-1000-03, 0069-1000-02) and images of labels with the new tradename.<br><br>Pfizer subsequently received approval to amend its FDA BLA License on December 16, 2021 to include its tris-sucrose formulation COVID-19 vaccine for use in individuals 16 and older (COMIRNATY). At that time, the FDA published a BLA package insert that included the approved new COVID-19 vaccine tradename COMIRNATY and listed 3 new NDCs (0069-2025-10, 0069-2025-25, 0069-2025-01) and images of labels with the new tradename.<br><br>At present, Pfizer does not plan to produce any product with these new NDCs and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution. As such, the CDC, AMA, and drug compendia may not publish these new codes until Pfizer has determined when the product will be produced with the BLA labels." |
| Moderna US, Inc. | BLA-licensed for ages 18+ | SPIKEVAX | 0.5 mL dose (same as original EUA formula) | 80777-100-99 | CARTON, 10 MULTI-DOSE VIALS, EACH VIAL CONTAINING 5.5 mL | NA | VIAL, 5.5 mL, MULTI-DOSE VIAL | SPIKEVAX products are not orderable at this time. NDCs are listed per FDA Structured Product Label (SPL) document for the BLA licensed product. These codes are not included in CDC Vaccine Code Set files at this time. Moderna has provided the following statement regarding the SPIKEVAX branded NDCs and labels: "Moderna received FDA BLA license on January 31, 2022, for its COVID-19 vaccine SPIKEVAX (COVID-19 Vaccine, mRNA) for use in individuals 18 and older. At that time, the FDA published a BLA package insert that included the new approved trade name SPIKEVAX and listed 2 new NDCs (80777-100-99, 80777-100-98).<br><br>At present, Moderna does not plan to produce any product with these new NDCs and labels over the next few months while EUA authorized Moderna COVID-19 Vaccine product is still available and being made available for U.S. distribution. As such, the CDC, AMA, and drug compendia may delay publishing these new codes until Moderna has determined when the product will be produced with the BLA labels." |
| | | | | 80777-100-98 | CARTON, 10 MULTI-DOSE VIALS, EACH VIAL CONTAINING 7.5 mL | NA | VIAL, 7.5 mL, MULTI-DOSE VIAL | |

Download the Preview Table *for Non-US vaccine administration only*: Excel Version

Preview Posting of COVID-19 Vaccine Codes and Crosswalks to be used for Non-US vaccine administration. All COVID-19 related CVX codes are associated to the Vaccine Group "COVID-19". Data as of 11/15/2021. CVX and MVX codes are identified for vaccines that have received emergency authorization from the World Health Organization (WHO), US Food and Drug Administration (FDA) or both. CVX codes have also been added without associated MVX for vaccines that are manufactured and administered outside the US but which have not been authorized by the WHO. The list of vaccines not authorized by the WHO may be incomplete. The list of vaccines indicated to be WHO-authorized will be updated periodically as the CDC monitors WHO published information.

| CVX Code | CVX Long Description | CVX Short Description | CVX Note | CVX Status | MVX Code | MVX Manufacturer | Product Tradename(s) |
|---|---|---|---|---|---|---|---|

Enclosure (5)

| CVX Code | CVX Long Description | CVX Short Description | CVX Note | CVX Status | MVX Code | MVX Manufacturer | Product Tradename(s) |
|---|---|---|---|---|---|---|---|
| 207 | SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 100 mcg or 50 mcg dose | COVID-19, mRNA, LNP-S, PF, 100 mcg or 50 mcg dose | EUA 12/18/2020, 2-dose vaccine. Used to record Moderna vaccines administered in the US and in non-US locations (includes tradename Spikevax) | Active | MOD | Moderna US, Inc. | Moderna COVID-19 Vaccine (non-US Spikevax) |
| 208 | SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 30 mcg/0.3mL dose | COVID-19, mRNA, LNP-S, PF, 30 mcg/0.3 mL dose | EUA 12/11/2020, 2-dose vaccine. Used to record Pfizer vaccines administered in the US and in non-US locations (includes tradename Comirnaty) | Active | PFR | Pfizer, Inc | Pfizer-BioNTech COVID-19 Vaccine (US-EUA), COMIRNATY (US-BLA), COMIRNATY (Non-US) |
| 210 | SARS-COV-2 (COVID-19) vaccine, vector non-replicating, recombinant spike protein-ChAdOx1, preservative free, 0.5 mL | COVID-19 vaccine, vector-nr, rS-ChAdOx1, PF, 0.5 mL | Potential EUA, 2-dose vaccine. AstraZeneca vaccine is authorized by the WHO and recognized towards immunity in the US. Non-US WHO authorized tradenames/identifiers include VAXZEVRIA, AZD1222, ChAdOx1 nCoV-19, COVISHIELD | Non-US | ASZ | AstraZeneca | AstraZeneca COVID-19 Vaccine (Non-US tradenames include VAXZEVRIA, COVISHIELD) |
| 212 | SARS-COV-2 (COVID-19) vaccine, vector non-replicating, recombinant spike protein-Ad26, preservative free, 0.5 mL | COVID-19 vaccine, vector-nr, rS-Ad26, PF, 0.5 mL | EUA 02/27/2021, 1-dose vaccine. Used to record Janssen/J&J vaccines administered in the US and in non-US locations | Active | JSN | Janssen | Janssen (J&J) COVID-19 Vaccine |
| 510 | SARS-COV-2 COVID-19 Inactivated Virus Non-US Vaccine Product (BIBP, Sinopharm) | COVID-19 IV Non-US Vaccine (BIBP, Sinopharm) | WHO authorized pandemic vaccine. Recognized towards immunity in US | Non-US | SPH | Sinopharm-Biotech | Sinopharm (BIBP) COVID-19 Vaccine |
| 511 | SARS-COV-2 COVID-19 Inactivated Virus Non-US Vaccine Product (CoronaVac, Sinovac) | COVID-19 IV Non-US Vaccine (CoronaVac, Sinovac) | WHO authorized pandemic vaccine. Recognized towards immunity in US | Non-US | SNV | Sinovac | Coronavac (Sinovac) COVID-19 Vaccine |
| 500 | SARS-COV-2 COVID-19 Non-US Vaccine, Specific Product Unknown | COVID-19 Non-US Vaccine, Product Unknown | Pandemic Non-US Covid Administration – specific CVX or product unknown | Non-US | | | |
| 501 | SARS-COV-2 COVID-19 Inactivated Virus Non-US Vaccine Product (QAZCOVID-IN) | COVID-19 IV Non-US Vaccine (QAZCOVID-IN) | Pandemic Non-US Vaccine not Authorized by WHO – not counted toward immunity in US | Non-US | | | |
| 502 | SARS-COV-2 COVID-19 Inactivated Virus Non-US Vaccine Product (COVAXIN) | COVID-19 IV Non-US Vaccine (COVAXIN) | Pandemic Non-US Vaccine Authorized by WHO 11-3-2021, recognized toward immunity in US, https://extranet.who.int/pqweb/vaccines/who-recommendation-bharat-biotech-international-ltd-covid-19-vaccine-whole-virion | Non-US | BBI | Bharat Biotech International Limited | COVAXIN (Bharat) COVID-19 Vaccine |
| 503 | SARS-COV-2 COVID-19 Live Attenuated Virus Non-US Vaccine Product (COVIVAC) | COVID-19 LAV Non-US Vaccine (COVIVAC) | Pandemic Non-US Vaccine not Authorized by WHO – not counted toward immunity in US | Non-US | | | |
| 504 | SARS-COV-2 COVID-19 Viral Vector Non-replicating Non-US Vaccine Product (Sputnik Light) | COVID-19 VVnr Non-US Vaccine (Sputnik Light) | Pandemic Non-US Vaccine not Authorized by WHO – not counted toward immunity in US | Non-US | | | |
| 505 | SARS-COV-2 COVID-19 Viral Vector Non-replicating Non-US Vaccine Product (Sputnik V) | COVID-19 VVnr Non-US Vaccine (Sputnik V) | Pandemic Non-US Vaccine not Authorized by WHO – not counted toward immunity in US | Non-US | | | |

Enclosure (5)

| CVX Code | CVX Long Description | CVX Short Description | CVX Note | CVX Status | MVX Code | MVX Manufacturer | Product Tradename(s) |
|---|---|---|---|---|---|---|---|
| 506 | SARS-COV-2 COVID-19 Viral Vector Non-replicating Non-US Vaccine Product (CanSino Biological Inc./Beijing Institute of Biotechnology) | COVID-19 VVnr Non-US Vaccine (CanSino Biological Inc./Beijing Institute of Biotechnology) | Pandemic Non-US Vaccine not Authorized by WHO – not counted toward immunity in US | Non-US | | | |
| 507 | SARS-COV-2 COVID-19 Protein Subunit Non-US Vaccine Product (Anhui Zhifei Longcom Biopharmaceutical + Institute of Microbiology, Chinese Academy of Sciences) | COVID-19 PS Non-US Vaccine (Anhui Zhifei Longcom Biopharmaceutical + Institute of Microbiology, Chinese Academy of Sciences) | Pandemic Non-US Vaccine not Authorized by WHO – not counted toward immunity in US | Non-US | | | |
| 508 | SARS-COV-2 COVID-19 Protein Subunit Non-US Vaccine Product (Jiangsu Province Centers for Disease Control and Prevention) | COVID-19 PS Non-US Vaccine (Jiangsu Province Centers for Disease Control and Prevention) | Pandemic Non-US Vaccine not Authorized by WHO – not counted toward immunity in US | Non-US | | | |
| 509 | SARS-COV-2 COVID-19 Protein Subunit Non-US Vaccine Product (EpiVacCorona) | COVID-19 PS Non-US Vaccine (EpiVacCorona) | Pandemic Non-US Vaccine not Authorized by WHO – not counted toward immunity in US | Non-US | | | |

# COVID-19 Emergency Use Authorization Recipient and Caregiver Fact Sheets

## Preview Posting of Codes for Emergency Use Authorization (EUA) Fact Sheets for Recipients and Caregivers

Vaccine information statements (VISs), used only for licensed vaccines, will not be available for COVID-19 vaccines while they are under Emergency Use Authorization (EUA). For vaccines under an EUA, the FDA requires a vaccine-specific Fact Sheet for Recipients and Caregivers be provided to vaccine recipients or their caregivers.

The COVID-19 vaccine-related codes are provided in anticipation of potential vaccine availability under an EUA. If a vaccine is not authorized, the code will be retired.

The FDA issued Emergency Use Authorization for the Moderna COVID-19 vaccine on Friday December 18, 2020. Information regarding that vaccine as well as both the EUA Provider Fact Sheet and the EUA Recipient and Caregiver Fact Sheets is now available on the following FDA web site link:

https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine

The FDA issued Emergency Use Authorization for the Pfizer BioNTech COVID-19 vaccine on Friday December 11, 2020. Information regarding that vaccine as well as both the EUA Provider Fact Sheet and the EUA Recipient and Caregiver Fact Sheets is now available on the following FDA web site link:

https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine

The FDA issued Emergency Use Authorization for the Janssen (Johnson & Johnson) COVID-19 vaccine on Saturday

Enclosure (5)

February 27, 2021. Information regarding that vaccine as well as both the EUA Provider Fact Sheet and the EUA Recipient and Caregiver Fact Sheets is now available on the following FDA web site link:

https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine

**The following downloadable VIS code files will include the new EUA Fact Sheet for Recipients records:**

- Excel version of table

| CVX Code | EUA Recipient/Caregiver Fact Sheet Description | Document Barcode String | Edition Date | Edition Status | HTML URL | PDF URL |
|---|---|---|---|---|---|---|
| 207 | COVID-19 Moderna Vaccine EUA Recipient-Caregiver Fact Sheet | 25308869830003491121060 1 | 1/31/2022 | Current | https://www.cdc.gov/vaccines/covid-19/eua/modernatx.html | https://www.cdc.gov/vaccines/covid-19/eua/modernatx.pdf |
| 208, 217 | COVID-19 Pfizer BioNTech EUA Recipient-Caregiver Fact Sheet – 12 years and older | 25308869830003321121050 1 | 1/31/2022 | Current | https://www.cdc.gov/vaccines/covid-19/eua/pfizer.html | https://www.cdc.gov/vaccines/covid-19/eua/pfizer.pdf |
| 218 | COVID-19 Pfizer BioNTech EUA Recipient-Caregiver Fact Sheet – Pediatric 5 – 11 years | 25308869830004241121100 1 | 1/3/2022 | Current | https://www.cdc.gov/vaccines/covid-19/eua/pfizer-children.html | https://www.cdc.gov/vaccines/covid-19/eua/pfizer-children.pdf |
| 219 | COVID-19 Pfizer BioNTech EUA Recipient-Caregiver Fact Sheet-Pediatric <5 yrs | 25308869830004861122010 1 | 3/1/2022 | Current | https://www.cdc.gov/vaccines/covid-19/eua/pfizer-children-under-5-years.html | https://www.cdc.gov/vaccines/covid-19/eua/pfizer-children-under-5-years.pdf |
| 212 | COVID-19 Janssen Vaccine EUA Recipient-Caregiver Fact Sheet | 25308869830003631121020 1 | 1/31/2022 | Current | https://www.cdc.gov/vaccines/covid-19/eua/janssen.html | https://www.cdc.gov/vaccines/covid-19/eua/janssen.pdf |

***Edition Date represents the date of update printed on the actual fact sheet document published by the FDA. It may not be the same as the EUA authorization date or the date embedded in the Document Barcode String.**

Page last reviewed: March 15, 2022

Enclosure (5)

August 23, 2021

RE: Pfizer-BioNTech COVID-19 Vaccine IMPORTANT PRODUCT INFORMATION

**Certain Pfizer-BioNTech COVID-19 Vaccine Lots authorized for Emergency Use comply with the Biologics License Application (BLA)**

COMIRNATY®
(COVID-19 Vaccine, mRNA)

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

Manufactured by
Pfizer Inc.
New York, NY 11017

US License No. 2229

Dear Healthcare Professional,

Pfizer, Inc. would like to provide you with updated and very important information related to the Pfizer-BioNTech COVID-19 Vaccine, authorized for emergency use by FDA under an Emergency Use Authorization (EUA). On August 23, 2021, FDA approved BioNTech's Biologics License Application (BLA) for COMIRNATY (COVID-19 Vaccine, mRNA), under U.S. License No. 2229. Many lots of Pfizer-BioNTech COVID-19 Vaccine are in circulation that were authorized for emergency use, and are labelled in accordance with the EUA. **Some of these lots comply with the recently approved BLA for COMIRNATY and are therefore considered "BLA-approved" lots for administration to individuals 16 years of age and older.** The lots that are BLA-approved for administration may be found at cvdvaccine-us.com/resources. For these lots, please see the COMIRNATY® full prescribing information for indication and usage, dosing and administration, and important safety information. This information can be found by scanning the QR code. **Please note, it is imperative that you not discard any available EUA lots. These lots continue to be authorized for use under EUA in individuals 12 years of age and older, and for use as a third dose in certain immunocompromised individuals. You can continue to use them up to the date of expiry.**

Sincerely,

Donna Boyce
Senior Vice President, Global Regulatory Affairs

BIONTECH

Enclosure (6)

Pfizer

2021TA035 v1.0

# If you plan to redistribute the Pfizer-BioNTech COVID-19 Vaccine, please read on...

COMIRNATY®
(COVID-19 Vaccine, mRNA)

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

Manufactured by
Pfizer Inc.
New York, NY 11017

US License No. 2229

| | |
|---|---|
| **WHAT?** | If you plan on redistributing the Pfizer-BioNTech COVID-19 Vaccine, you must include at least one copy of the letter with QR code in each of the smaller, portable packaging containers being used for transport. |
| **WHY?** | Once the Pfizer-BioNTech COVID-19 Vaccine arrives at its final destination, the QR code may be used to look up the lot number on the carton to determine if the product is BLA-approved. |
| **HOW?** | To create additional copies of the letter to include in smaller transport containers, you may:<br>• Make copies of this letter using a copy machine<br>• Make printouts by visiting cvdvaccine-us.com/resources |

For questions related to this notification please contact Pfizer Customer Service at 1-800-666-7248.

BIONTECH

Enclosure (6)

Pfizer

2021TA035 v1.0

## Additional Lot Details – Lot Numbers

| |
|---|
| *FD7220* |
| *FE3592* |
| *FF2587* |
| *FF2588* |
| *FF2590* |
| *FF2593* |
| *FF8841* |
| *FH8027* |
| *FH8028* |

# Expiry Information for All Three Vaccine Presentations

**Document Updated as of January 3, 2022.**

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.

Regardless of storage condition, **orange cap** and **gray cap** vaccine vials should not be used after 9 months from the **date of manufacture** printed on the vial and cartons. The **purple cap** vaccine vials with an **expiry date** of September 2021-February 2022 (printed on the label) may remain in use for 3 months beyond the printed date if vials are maintained in approved storage conditions (-90°C to -60°C, -130°F to -76°F).[1-3]

**Expiry information for Ages 5 through 11 DILUTE BEFORE USE Orange Cap presentation and Ages 12 years and older DO NOT DILUTE Gray Cap presentation**

| Printed Manufacturing Date | 9-Month Expiry Date |
|---|---|
| 06/2021 | 28-Feb-2022 |
| 07/2021 | 31-Mar-2022 |
| 08/2021 | 30-Apr-2022 |
| 09/2021 | 31-May-2022 |
| 10/2021 | 30-Jun-2022 |
| 11/2021 | 31-Jul-2022 |
| 12/2021 | 31-Aug-2022 |
| 01/2022 | 30-Sep-2022 |
| 02/2022 | 31-Oct-2022 |

**Expiry information for Ages 12 years and older DILUTE BEFORE USE Purple Cap presentation**

| Printed Expiry Date | Updated Expiry Date |
|---|---|
| September 2021 | December 2021 |
| October 2021 | January 2022 |
| November 2021 | February 2022 |
| December 2021 | March 2022 |
| January 2022 | April 2022 |
| February 2022 | May 2022 |

## Important Safety Information and Indication & Authorized Use

### 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).

*Important Safety Information, Indication & Authorized Use information continued on next page.*

**Please see additional Important Safety Information and Indication & Authorized Use on pages 2 and 3.**
**Before administration of the vaccine, please scroll down and click to review the full Prescribing Information and the respective EUA Fact Sheets.**

Enclosure (8)

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

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, 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%).

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%).

### Indication & Authorized Use

The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older, 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 should not be used for individuals 5 through 11 years of age because of the potential for vaccine administration errors, including dosing errors.

### 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.

*Important Safety Information, Indication & Authorized Use continued on next page.*

**Please see additional Important Safety Information and Indication & Authorized Use on pages 1 and 3.**
**Before administration of the vaccine, please scroll down and click to review the full Prescribing Information and the respective EUA Fact Sheets.**

Enclosure (8)

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

## Authorized Use

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 10 mcg modRNA 2-dose primary series to individuals 5 through 11 years of age
- a 30 mcg modRNA 2-dose primary series to individuals 12 years of age and older
- a 10 mcg modRNA third primary series dose to individuals 5 through 11 years of age who have been determined to have certain kinds of immunocompromise
- a 30 mcg modRNA third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a 30 mcg modRNA single 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 30 mcg modRNA single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized 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

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

- a 30 mcg modRNA 2-dose primary series to individuals 12 through 15 years of age
- a 30 mcg modRNA third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a 30 mcg modRNA single 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 30 mcg modRNA single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized 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

**Please see additional Important Safety Information and Indication & Authorized Use on pages 1 and 2.**

**Before administration of the vaccine, please click 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)(5 through 11 years of age), DILUTE BEFORE USE, Orange Cap. Pfizer and BioNTech; January 3, 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; January 3, 2022. **3.** 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; January 3, 2022.

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

Manufactured by
Pfizer Inc.
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.



Enclosure (8)

# Q&A for Comirnaty (COVID-19 Vaccine mRNA)

Español (https://www.fda.gov/vaccines-blood-biologics/preguntas-y-respuestas-sobre-comirnaty-vacuna-de-arnm-contra-el-covid-19)

**How did the FDA arrive at the decision to approve Comirnaty (COVID-19 Vaccine mRNA)? What is different now when compared to the December 2020 authorization of Pfizer-BioNTech COVID-19 Vaccine?**

FDA conducted a thorough evaluation of the data and information submitted in the Biologics License Application (BLA) for Comirnaty before making a determination that the vaccine is safe and effective in preventing COVID-19 in individuals 16 years of age and older.

The EUA (/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19) for the Pfizer-BioNTech COVID-19 Vaccine for individuals 16 years of age and older was based on safety and effectiveness data from a randomized, controlled, blinded ongoing clinical trial in approximately 18,000 individuals who received the vaccine and approximately 18,000 who received a placebo. The vaccine was 95% effective in preventing COVID-19 disease among these clinical trial participants with eight COVID-19 cases in the vaccine group and 162 in the placebo group. The duration of safety follow-up for the vaccinated and placebo participants was a median of two months after receiving the second dose.

Follow-up data from this ongoing clinical trial was analyzed by FDA to determine the safety and effectiveness of Comirnaty. The updated analysis to determine effectiveness for individuals 16 years of age and older included approximately 20,000 Comirnaty and 20,000 placebo recipients who did not have evidence of SARS-CoV-2 infection through seven days after the second dose. Overall, the vaccine was 91% effective, with 77 cases of COVID-19 occurring in the vaccine group and 833 COVID-19 cases in the placebo group.

The safety was evaluated in approximately 22,000 Comirnaty and 22,000 placebo recipients 16 years of age and older. More than half of the vaccine and placebo recipients were followed for safety for at least four months after the second dose. After issuance of the EUA, participants were unblinded in a phased manner over a period of months to offer placebo participants Comirnaty. Overall, in blinded and unblinded follow-up, approximately 12,000 Comirnaty recipients have been followed for at least 6 months.

**How safe and effective is Comirnaty (COVID-19 Vaccine mRNA)?**

Overall, the vaccine was 91% effective in preventing COVID-19 disease, with 77 cases of COVID-19 occurring in the vaccine group and 833 COVID-19 cases in the placebo group.

The most commonly reported side effects by those clinical trial participants who received Comirnaty were pain, redness and swelling at the injection site, fatigue, headache, muscle pain, chills, joint pain and fever.

The FDA conducted a rigorous evaluation of post-authorization safety surveillance data pertaining to myocarditis and pericarditis following administration of Pfizer-BioNTech COVID-19 Vaccine and determined that the data demonstrate increased risks, particularly within the seven days following the second dose. The observed risk is higher among males under 40 years of age compared to females and older males. The observed risk is highest in males 12 through 17 years of age. Available data from short-term follow-up suggest that most individuals have had resolution of symptoms. However, some individuals required intensive care support. Information is not yet available about potential long-term health outcomes. The Comirnaty Prescribing Information (/media/151707/download) includes a warning about these risks.

**What are the most commonly reported side effects by those who received Comirnaty (COVID-19 Vaccine mRNA)?**

The most commonly reported side effects by those clinical trial participants who received Comirnaty were pain, redness and swelling at the injection site, fatigue, headache, muscle pain, chills, joint pain, and fever.

**How long will Comirnaty provide protection?**

Data are not yet available to inform about the duration of protection that the vaccine will provide.

**Can people who have already had COVID-19 get Comirnaty?**

Yes. Among the participants in the study that the FDA evaluated for the December 2020 authorization, relatively few confirmed COVID-19 cases occurred overall among clinical study participants with evidence of SARS-CoV-2 infection prior to vaccination.

Current scientific evidence suggests that individuals previously infected with SARS-CoV-2, including individuals who have had COVID-19, may be at risk of reinfection and developing COVID-19 again and could benefit from vaccination. Furthermore, available data suggest that the safety profile of the vaccine in previously infected individuals is just as favorable as in previously uninfected individuals.

**Does Comirnaty protect against asymptomatic SARS-CoV-2 infection (i.e. the individual is infected with SARS-CoV-2, but does not have signs or symptoms of COVID-19)?**

It is not known if Comirnaty protects against asymptomatic SARS-CoV-2 infection.

**If a person has received Comirnaty, will the vaccine protect against transmission of SARS-CoV-2 from individuals who are infected despite vaccination?**

Most vaccines that protect from viral illnesses also reduce transmission of the virus that causes the disease by those who are vaccinated. While it is hoped this will be the case, the scientific community does not yet know if Comirnaty will reduce such transmission.

**Can Comirnaty cause infertility in women?**

There is no scientific evidence to suggest that the vaccine could cause infertility in women. In addition, infertility is not known to occur as a result of natural COVID-19 disease, further demonstrating that immune responses to the virus, whether induced by infection or a vaccine, are not a cause of infertility. Reports on social media have falsely asserted that the vaccine could cause infertility in women and the FDA is concerned that this misinformation may cause women to avoid vaccination to prevent COVID-19, which is a potentially serious and life-threatening disease. SARS-CoV-2 is the virus that causes COVID-19. The symptoms of COVID-19 vary and are unpredictable; many people have no symptoms or only mild disease, while some have severe respiratory disease including pneumonia and acute respiratory distress syndrome (ARDS), leading to multi-organ failure and death. Comirnaty is a mRNA vaccine. It contains a piece of the SARS-CoV-2 virus's genetic material that instructs cells in the body to make the virus's distinctive "spike" protein. After a person is vaccinated, their body produces copies of the spike protein, which does not cause disease, and triggers the immune system to learn to react defensively, producing an immune response against SARS-CoV-2. Contrary to false reports on social media, this protein is not the same as any involved in the formation of the placenta.

**After FDA granted the emergency use authorization of the Pfizer BioNTech COVID-19 Vaccine were clinical trial participants unblinded so that the placebo recipients could be offered the vaccine?**

Yes. After issuance of the EUA, clinical trial participants were unblinded in a phased manner over a period of months to offer the authorized Pfizer-BioNTech COVID-19 Vaccine to placebo participants. These participants were followed for safety outcomes. Overall, in blinded and unblinded follow-up, approximately 12,000 Pfizer-BioNTech COVID-19 Vaccine recipients have been followed for at least 6 months.

**Does the emergency use authorization (EUA) for Pfizer-BioNTech COVID-19 Vaccine remain in effect after the approval?**

Yes. Pfizer-BioNTech COVID-19 Vaccine is authorized for emergency use and is available under the EUA as a two dose primary series in individuals 5 years of age and older, as a third primary series dose for individuals 5 years of age and older who have been determined to have certain kinds of immunocompromise, and as a single booster dose for individuals 12 years of age and older at least 5 months after completing a primary series of the Pfizer-BioNTech COVID-19 Vaccine or Comirnaty.

The Pfizer-BioNTech COVID-19 Vaccine is also authorized for use as a heterologous (or "mix and match") single booster dose for individuals 18 years of age and older following completion of primary vaccination with a different authorized COVID-19 vaccine.

**How is Comirnaty (COVID-19 Vaccine, mRNA) related to the Pfizer-BioNTech COVID-19 Vaccine authorized for emergency use?**

The FDA-approved Comirnaty (COVID-19 Vaccine, mRNA) and the FDA-emergency use authorized Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older, when prepared according to their respective instructions for use, can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. Therefore, providers can use doses distributed under EUA to administer the vaccination series as if the doses were the licensed vaccine. For

purposes of administration, doses distributed under the EUA are interchangeable with the licensed doses. The Vaccine Information Fact Sheet for Recipients and Caregivers (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine#additional) provides additional information about both the approved and authorized vaccines.

**Can Comirnaty and the Pfizer-BioNTech COVID-19 Vaccine be used interchangeably?**

The FDA-approved Comirnaty (COVID-19 Vaccine, mRNA) and the two EUA-authorized formulations of the Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older when prepared according to their respective instructions for use, can be used interchangeably.

The formulation of the Pfizer-BioNTech COVID-19 Vaccine authorized for use in children 5 through 11 years of age differs from the formulations authorized for older individuals. The Pfizer-BioNTech COVID-19 Vaccine authorized for use in children 5 through 11 years of age should not be used interchangeably with Comirnaty.

## Hoppe Capt Joshua P

**From:** Hoppe Capt Joshua P
**Sent:** Thursday, March 17, 2022 3:49 PM
**To:** LCDR
**Cc:** LT USN BRMEDCLINIC (USA);
**Subject:** RE: Memos pertaining to interchangeability of Pfizer and Comirnaty
**Attachments:** Pfizer-BioNTech BLA-approved Lots memo_23 Aug 21.pdf; Pfizer 9 additional-lot-details-v3.pdf; Expiry_Document_3 Jan 2022.pdf

Good Afternoon Sir,

Attached is the Pfizer-BioNTech BLA-approved lots memo that was released when COMIRNATY was approved along with the 9 Lot numbers listed. I pulled them from this site: https://www.cvdvaccine-us.com/16-up-yearsold/resources By implication, Pfizer is saying anything else isn't compliant unless it is labeled and marketed as Comirnaty or Spikevax appropriately.

Also attached is the Expiration document that I found on the same site for reference. I didn't see anything that specifically states the expiration is the last day of the month, but I called Pfizer and that's what they confirmed as well though they did not have any official document or guidance they could send me.

My inquiry would be if you are able to search the system to see if any of these lot numbers are still active or present anywhere in the supply chain. Nowhere I have checked so far has had these, Comirnaty, or Spikevax. Thanks for your assistance with this.

Semper Fidelis,

Capt Joshua "Hippity" Hoppe
[redacted]ASO/S-5/NATOPS/Education Officer
Office:
@usmc.mil

-----Original Message-----
From: T USN BRMEDCLINIC (USA)
<[redacted]mail.mil>
Sent: Thursday, March 17, 2022 12:57 PM
To: @usmc.mil>
Cc: Hoppe Capt Joshua P @usmc.mil>
Subject: FW: Memos pertaining to interchangeability of Pfizer and Comirnaty



Enclosure (10)

V/r,

MD

LT, MC (FS), USN

Flight Surgeon

MCAS

O

C:

USN: @mail.mil mail.mil>

USMC: @usmc.mil

From: CDR USN BRMEDCLINIC (USA)
< @mail.mil>
Sent: Thursday, March 17, 2022 9:43 AM
To: LT USN BRMEDCLINIC (USA)
< mail.mil>
Subject: Memos pertaining to interchangeability of Pfizer and Comirnaty

Good Morning LT ,

Attached are a couple memos that discuss the interchangeability of the vaccines. We do not have any vaccine on order. When we order it, we have no control over whether the vaccine we receive says “Comirnaty” or “Spikevax.”

V/R

FACHE, PMP

LCDR, MSC, USN

Officer in Charge

NMRTU

NBHC