Comirnaty (COVID-19 Vaccine, mRNA)

What data did FDA evaluate to support the September 11, 2023, approval of a single dose of Comirnaty for individuals 12 years of age and older?

The effectiveness of a single dose of Comirnaty for individuals 12 years of age and older, regardless of prior COVID-19 vaccination status, is supported by FDA's previous determination of the effectiveness of Comirnaty and analysis of immune response data from a clinical study among approximately 260 individuals 18 through 85 years of age who were COVID-19 unvaccinated and had evidence of prior SARS-CoV-2 infection. These individuals received a single dose of an investigational bivalent Pfizer-BioNTech COVID-19 vaccine, and their immune responses were compared to the immune responses of approximately 270 participants without evidence of prior SARS-CoV-2 infection who received two doses of Comirnaty (Original monovalent), one month apart. The immune response data demonstrated that individuals who had prior evidence of infection responded adequately to a single dose of vaccine.

The safety of a single dose of Comirnaty for individuals 12 years of age and older, regardless of prior COVID-19 vaccination status, is supported by FDA's previous determination of the safety of Comirnaty and data from a clinical study among approximately 700 individuals 12 years of age and older who received a second booster dose with Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA4.BA.5). The most commonly reported side effects were pain at the injection site, fatigue, headache, muscle pain, chills, joint pain and fever.

The data accrued with the authorized and investigational bivalent Pfizer-BioNTech COVID-19 vaccines are relevant to Comirnaty because all of these vaccines have a similar manufacturing process.

NEW YORK STATE | Department of Health

New York State Department of Health - Bureau of Immunization

COVID-19 Vaccine Screening and Consent Form for Adults

VACCINE REQUESTED:

☐ Moderna monovalent 2023-2024

☐ Pfizer monovalent 2023-2024

Dates of previous COVID 19 vaccination:

_____

_____

_____

_____

Recipient Name (please print)		Preferred Name	
DOB AGE			Email Address
Address City State		Zip	Phone
DOB	Sex Assigned at Birth **Key:** M – Male Indicate Sex Below: F – Female		
Primary Insurance Name-Enter **'NONE'** if NO insurance		Primary Insurance ID#	
Subscriber Name/DOB Relation to Patient		Primary Insurance Group # Primary Insurance Phone # BIN: PCN:	
Date of Last COVID Vaccine: Did you Receive a Dose outside of NY State:			
Clinic/Office Site Where Vaccine is Administered		Primary Care Physician Address/Phone Number	

Screening Questionnaire: The following questions will help us determine if there is any reason COVID-19 vaccine cannot be given today. If you answer "yes" to any question, it does not necessarily mean the vaccine cannot be given. It just means additional questions may be asked. If a question is not clear, please ask a healthcare provider to explain it.

1.	Are you feeling sick today?	☐ Yes	☐ No	☐ Unknown
2.	In the last 10 days, have you had a COVID-19 test because you had symptoms and are still awaiting your test results or been told by a health care provider or health department to isolate or quarantine at home due to COVID-19 infection or exposure?	☐ Yes	☐ No	☐ Unknown
3.	How old will the person be on the day of vaccination? _____			
4.	Has the person to be vaccinated ever received a dose of COVID-19 vaccine? • If yes, which product was administered? ☐ Pfizer-BioTech ☐ Janssen (Johnson & Johnson) ☐ Another product ☐ Moderna ☐ Novavax _____ • How many doses of COVID-19 vaccine were previously administered? _____	☐ Yes	☐ No	☐ Unknown
5.	Have you ever had an immediate allergic reaction (e.g., hives, facial swelling, difficulty breathing, anaphylaxis) to any vaccine, injection, or shot or to any component of the COVID-19 vaccine, or a severe allergic reaction (anaphylaxis) to anything?	☐ Yes	☐ No	☐ Unknown
6.	Are you moderately or severely immunocompromised due to one or more of the medical conditions or receipt of immunosuppressive medications or treatments listed below? 1) Active treatment for solid tumor and 2)hematologic malignancies, 3) Receipt of solid-organ transplant and taking immunosuppressive therapy, 4) Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy), 5) Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, WiskottAldrich syndrome), 6) Advanced or untreated HIV infection, 7) Active treatment with high-dose corticosteroids (i.e., 20 mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.	☐ Yes	☐ No	☐ Unknown
7.	Are you pregnant or considering becoming pregnant?	☐ Yes	☐ No	☐ Unknown
8.	Do you have a bleeding disorder, a history of blood clots or are you taking a blood thinner?	☐ Yes	☐ No	☐ Unknown
9.	Do you have a history of myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining around the heart)?	☐ Yes	☐ No	☐ Unknown
11.	Do you have a history of MIS-C or MIS-A (multisystem inflammatory syndrome in children or multisystem inflammatory syndrome in adults)?	☐ Yes	☐ No	☐ Unknown

Emergency Use Authorization

The FDA has made the COVID-19 vaccine available under an emergency use authorization (EUA). The EUA is used when circumstances exist to justify the emergency use of drugs and biological products during an emergency, such as the COVID-19 pandemic. This vaccine has not undergone the same type of review as an FDAapproved or cleared product. However, the FDA's decision to make the vaccine available is based on the totality of scientific evidence available, showing that known and potential benefits of the vaccine outweigh the known and potential risks. The Novavax COVID-19 vaccine is EUA authorized for those individuals 12 years and older. Please note: FDA approved the Pfizer-BioNTech COVID-19 vaccine in individuals 12 years of age and older; and approved the Moderna COVID-19 vaccine in individuals 18 years of age and older. These vaccines continue to be available under an EUA for certain populations, including Pfizer-BioNTech COVID-19 vaccine for those individuals 6 months through 11 years old, and Moderna COVID-19 vaccine for individuals 6 months through 17 years old and for the administration of an additional dose in the populations set forth in the consent section below.

Emergency Use Instruction

Emergency Use Instructions (EUIs) are issued by the CDC to provide information about emergency use of FDA-approved medical products that may not be included in or differ in some way from the information provided in the FDA-approved labeling (package insert). The COVID-19 vaccine by Pfizer-BioNTech is an FDA-approved COVID-19 vaccine (brand name Comirnaty, mRNA) to prevent COVID-19 in persons 12 years of age and older. CDC is issuing EUI to provide information about use of this vaccine as an additional primary dose in certain immunocompromised persons (12 years of age and older) and a booster dose in certain adults (18 years of age and older) who received certain **non-FDA authorized or approved COVID-19 vaccine** (e.g., certain vaccines available outside of the United States or from clinical trial participation).

Consent

I have read, or had explained to me, the information sheet about the COVID-19 vaccination. I understand that if my vaccine requires two doses, I will need to be administered (given) two doses to be considered fully vaccinated. Further, I understand that a booster dose of COVID- 19 vaccine is recommended at least 2 months following the completion of a COVID-19 vaccine primary series or a monovalent booster dose to increase my protection.

I have had a chance to ask questions which were answered to my satisfaction (and ensured the person named above for whom I am authorized to provide surrogate consent was also given a chance to ask questions). I understand the benefits and risks of the vaccination as described.

I request that the COVID-19 vaccination be given to me (or the person named above for whom I am authorized to make this request and provide surrogate consent). I understand there will be no cost to me for this vaccine. I understand that any monies or benefits for administering the vaccine will be assigned and transferred to the vaccinating provider, including benefits/monies from my health plan, Medicare or other third parties who are financially responsible for my medical care. I authorize release of all information needed (including but not limited to medical records, copies of claims and itemized bills) to verify payment and as needed for other public health purposes, including reporting to applicable vaccine registries.

Recipient/Surrogate/Guardian Signature Date / Time Print Name Relationship to Patient (if other than recipient)

Area Below to be Completed by Vaccinator. Which vaccine is the patient receiving today?					
Vaccine Name	**Dosage**	**Route/Site**		**Manufacturer & Lot #**	**EUA Fact Sheet Date**
Pfizer/BioNTech Monovalent 2023-2024 Formulation	□ 0.3mL	□ IM Left Deltoid □ IM Right Deltoid			
Moderna Monovalent 2023-2024 Formulation	□ 0.5 mL	□ IM Left Deltoid □ IM Right Deltoid			
Accounting for any previous vaccine doses administered, which number dose is this? _____					

□ I have provided the patient (and/or parent, guardian, or surrogate, as applicable) with information about the vaccine and consent to vaccination was obtained.

Vaccinator Signature: _____

Use of this form is optional. Form adapted from the CDC screening checklist **Updated September 14, 2023**

NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

JAMES V. McDONALD, M.D., M.P.H.
Commissioner

JOHANNE E. MORNE, M.S.
Acting Executive Deputy Commissioner

CONFIDENTIAL

Declination of COVID-19 Comirnaty Vaccine

My employer, the NYS Veterans Home at Batavia, recommends that I receive the COVID-19 Comirnaty vaccine to protect myself, patients, staff, and others in the healthcare facility.

I acknowledge that I have read, or had explained to me, the Coronavirus Disease (COVID-19) General Information handout Fact Sheet regarding the COVID-19 Comirnaty vaccine.

I have had the opportunity to ask questions, which have been answered to my satisfaction, and understand the benefits and risks of the vaccine as described.

I understand that if I decline the vaccine, I may change my mind and request to be boosted later, with the understanding that the vaccine will be based on the availability at that time.

☐ I choose to decline the COVID-19 Comirnaty vaccine.

☐ I understand that I can change my mind at any time and accept the COVID-19 Comirnaty vaccine.

Signature: _____ Date: _____

Name (print): _____

Department: _____