



CAYUGA COUNTY HEALTH DEPARTMENT

"We promote and protect the health and well-being of the individuals, families and the community we serve."

Kathleen D. Cuddy, MPH
Director of Public Health

November 10, 2021

Dear Parent/Guardian:

As you're aware, the U.S. Food and Drug Administration recently approved the emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine to include children 5 through 11 years of age. As such, the Cayuga County Health Department is pleased to have the opportunity to provide the vaccine to students of the Cato-Meridian Central School District on Monday, November 22, 2021. The **first dose clinic** will be from 9-11:30 AM in the Round Table Cafeteria located in the Cato-Meridian Elementary School. FYI-The **second dose clinic** is already scheduled for Friday, December 14, 2021 in the same location from 1-3 PM.

If you are interested in having your child receive the COVID-19 vaccine, please review and complete the attached Consent Form and Medical Screening Form. All forms must be returned to your child's school by Thursday, November 18th.

You will be able to attend with your child.

Please note the Pfizer-BioNTech COVID-19 Vaccine is a two-shot series spaced three weeks apart. The Health Department plans to return to each school to provide the second dose. For the second dose clinic, you will need to complete another Medical Screening Form, but not the Consent Form. Consenting to the 1st dose also gives your consent for your child to receive the 2nd dose. Should you have any questions or concerns, you are welcome to contact your school nurse or the Cayuga County Health Department.

Thank you and know that your willingness to participate is appreciated. Vaccination works better when we do it together.

Sincerely,

Deanna Ryan, M.S.
Supervising Public Health Administrator

Attachments: Medical Screening Form, Minor Consent Form and Vaccine Information Fact Sheet



Cayuga County Health Department
 School Based Clinic Screening Form (5 – 11)
 Pfizer COVID-19 Vaccination



Patient Name: _____ Patient DOB: _____

School District: _____

Please answer the following screening questions completely on behalf of your child:

1. Are you between the ages of 5 and 11 years old? ___ Yes ___ No
2. Are you 12 years old or older? ___ Yes ___ No
3. Are you feeling sick today? ___ Yes ___ No
4. 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 healthcare provider or health department to isolate or quarantine at home due to COVID-19 infection or exposure? ****Please note that if you child has recently tested positive for COVID-19 they must be at minimum 14 days past their 10th day of isolation and symptom free.** ___ Yes ___ No
5. Have you been treated with antibody therapy or convalescent plasma for COVID-19 in the past 90 days (3 months)? If yes, when was your last dose? **** Please note if you have received any antibody or convalescent plasma treatment you must wait 90 days (3 months) from your last treatment before receiving the vaccine.** ___ Yes _____ Date of last Dose ___ No
6. Have you ever had an immediate allergic reaction, such as hives, face swelling, difficulty, breathing or 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
If yes please answer the following additional questions regarding the reaction:
 What was the reaction? _____
 What was the medication? _____
 How was the medication administered? (Orally, intravenous (IV) or intramuscular (IM)) _____
7. Do you have cancer, leukemia, HIV/AIDS, a history of autoimmune disease or any other conditions that weaken the immune system? If yes, have you spoken with your healthcare provider regarding vaccination? ___ Yes ___ No
8. Do you take any medications that affect your immune system, such as cortisone, prednisone or other steroids, anticancer drugs, or have you had any radiation treatments? ___ Yes ___ No
9. Do you have a bleeding disorder, a history of blood clots or are you taking a blood thinner? ___ Yes ___ No

10. Do you have a history of myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining around the heart)? Yes No
11. Have you received a previous dose of the Pfizer, Moderna or Janssen COVID-19 vaccine? Yes No
12. Have you received a previous dose of a COVID-19 vaccine authorized by the WHO but not by the FDA (AstraZeneca – VAXZEVRIA, Sinovac – CORONAVAC, Serum Institute of India – COVISHIELD, Sinopharm/BIBP)? Yes No

Parent/Guardian (Signature)

Date

Print Name

Relationship to Child

Date: _____
Vaccinator: _____
Lot No. _____
 Right Deltoid Left Deltoid



Pfizer-BioNTech COVID-19 Vaccine Consent Form for Children 5-11 Years of Age



Section 1: Information about the child to receive Pfizer-BioNTech COVID-19 Vaccine (please print):

Child's Name (Last, First, MI) Date of Birth Age
(mm/dd/yyyy)

Street Address

City State Zip Code

Parent/Guardian Name Phone Number

Health Insurance: COVID-19 vaccines are 100% free to all individuals in the U.S. Health insurance is not required to receive the vaccine. We do request insurance information because the health department will be seeking reimbursement for administration costs. Only insurance companies or the federal government can be billed for vaccine administration fees, not patients. There is NO out-of-pocket or co-pay costs for the vaccine.

If I have health insurance that covers the child named above and sign this consent, you are giving permission for your insurance company to be billed for the costs of administering the Pfizer-BioNTech COVID-19 Vaccine. The government is paying for the Pfizer-BioNTech COVID-19 Vaccine itself, and you will not be billed for that portion of the cost of the child's immunization.

Patient Name: _____ Date of Birth: _____

Name of Insurance: _____

Policy #: _____

Policy Holder Name: _____ Date of Birth: _____

Relationship to Patient: _____

Please check if the child does not have health insurance.

Section 2: Information on the risks and benefits of the PfizerBioNTech COVID-19 Vaccine

The Pfizer-BioNTech COVID-19 Vaccine may prevent the person vaccinated from getting COVID-19. There is no U.S. Food and Drug Administration (FDA)-approved vaccine to prevent COVID-19. However, the FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 in individuals 5 - 11 years of age under an Emergency Use Authorization (EUA).

The PfizerBioNTech COVID-19 Vaccine is administered as a 2-dose series, 3 weeks apart, into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine may not protect everyone. Side effects that have been reported with the Pfizer-BioNTech COVID-19 Vaccine include injection site pain, tiredness, headache, muscle pain, chills, joint pain, fever, injection site swelling, injection site redness, nausea, feeling unwell, and swollen lymph nodes. There is a remote chance that the Pfizer-BioNTech COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Pfizer-BioNTech COVID-19 Vaccine. For this reason, a vaccination provider may ask the person receiving the vaccine to stay at the place where they received their vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include difficulty breathing, swelling of the face and throat, a fast heartbeat, and/or a bad rash all over the body.

The Pfizer-BioNTech COVID-19 *Vaccine Information Fact Sheet for Recipients and Caregivers about the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) For Use in Individuals 5 Through 11 Years of Age* is attached hereto.

Section 3: Consent

CONSENT FOR MINOR'S VACCINATION: I have reviewed the information on risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine in Section 2 above and understand the risks and benefits. In providing my consent below, I agree that:

1. I have reviewed this consent form, and I understand that the Vaccine Information Fact Sheet includes more detailed information about the potential risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine.
2. I have the legal authority to consent to have the child named above vaccinated with the Pfizer-BioNTech COVID-19 Vaccine.
3. I understand I am not required to accompany the child named above to their vaccination appointment and that, by giving my consent below, the child will receive the Pfizer-BioNTech COVID-19 Vaccine whether or not I am present at the vaccination appointment.
4. In accordance with Section 2168 of the Public Health Law which governs vaccination reporting for school-aged persons under the age of 19, I understand the child's COVID-19 vaccination record will be linked to his/her existing records with the New York State Immunization Information System (NYSIIS)

I GIVE CONSENT for the child named at the top of this form to get vaccinated with the Pfizer-BioNTech COVID-19 Vaccine and have reviewed and agree to the information included in Section 3 of this form. (If this consent is not signed, dated and returned, the child will not be vaccinated.)

Signature of Legally Authorized Representative

Date

COVID-19 vaccines are *safe, effective and free* for kids 5 and older



The Pfizer COVID-19 vaccine for kids 5-11 will protect them from serious illness and get them back to safely being with their family and friends.



There were no serious safety concerns or serious side effects noted in the clinical trials.

Clinical trials began in March 2021. The first phase of the trial initially enrolled 4,500 children ages six months to 11 years in more than 90 clinical trial sites around the world.



More than 3,000 children ages 5-11 participated in the trials.

This is comparable to the number included in many similar clinical trials with children. Trials included volunteers from different races and ethnicities, including Black and Hispanic/Latinx volunteers (77% white, 6% Black, 8% Asian, 17% Hispanic/Latino, 7% multiracial).



Children are given two doses of the Pfizer vaccine. Each dose is one third the amount given to people 12 and older.



The vaccine is effective.

It produced similar immune responses in children 5-11 as in older kids and adults ages 16 to 25.



The Food and Drug Administration (FDA) reviews trials to determine if vaccines are safe.

An independent, scientific committee checks the work. Vaccines are authorized and the Centers for Disease Control and Prevention (CDC) recommends their use.



Temporary side effects for kids 5-11 are similar to older kids and adults. Your child may experience a temporarily sore arm, headache and being tired or achy for a day or so. Myocarditis, or inflammation of the heart muscle, is an extremely rare side effect with mostly mild cases. People usually recover on their own or need minimal treatment. No cases of myocarditis were seen during the clinical trials, ongoing monitoring will continue.

**VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS
ABOUT THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT
CORONAVIRUS DISEASE 2019 (COVID-19) FOR USE IN INDIVIDUALS
5 THROUGH 11 YEARS OF AGE**

FOR 5 THROUGH 11 YEARS OF AGE

Your child is being offered the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.

This Vaccine Information Fact Sheet for Recipients and Caregivers comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine for use in individuals 5 through 11 years of age.¹

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to provide a two-dose primary series to individuals 5 through 11 years of age.

This Vaccine Information Fact Sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, which your child may receive because there is currently a pandemic of COVID-19. Talk to your child's vaccination provider if you have questions.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOUR CHILD GETS THIS VACCINE

WHAT IS COVID-19?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness leading to death. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

For more information on EUA, see the “**What is an Emergency Use Authorization (EUA)?**” section at the end of this Fact Sheet.

¹ You may receive this Vaccine Information Fact Sheet even if your child is 12 years old. Children who will turn from 11 years to 12 years of age between their first and second dose in the primary regimen may receive, for either dose, either: (1) the Pfizer-BioNTech COVID-19 Vaccine formulation authorized for use in individuals 5 through 11 years of age; or (2) COMIRNATY or one of the Pfizer-BioNTech COVID-19 Vaccine formulations authorized for use in individuals 12 years of age and older.

WHAT SHOULD YOU MENTION TO YOUR CHILD'S VACCINATION PROVIDER BEFORE YOUR CHILD GETS THE VACCINE?

Tell the vaccination provider about all of your child's medical conditions, including if your child:

- has any allergies
- has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- has a fever
- has a bleeding disorder or is on a blood thinner
- is immunocompromised or is on a medicine that affects your child's immune system
- is pregnant
- is breastfeeding
- has received another COVID-19 vaccine
- has ever fainted in association with an injection

HOW IS THE VACCINE GIVEN?

The Pfizer-BioNTech COVID-19 Vaccine will be given to your child as an injection into the muscle.

The vaccine is administered as a 2-dose series, 3 weeks apart.

The vaccine may not protect everyone.

WHO SHOULD NOT GET THE VACCINE?

Your child should not get the vaccine if your child:

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

WHAT ARE THE INGREDIENTS IN THE VACCINE?

The vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), tromethamine, tromethamine hydrochloride, sucrose, and sodium chloride.

HAS THE VACCINE BEEN USED BEFORE?

Millions of individuals 12 years of age and older have received the Pfizer-BioNTech COVID-19 Vaccine under EUA since December 11, 2020. In a clinical trial, approximately 3,100 individuals 5 through 11 years of age have received at least 1 dose of Pfizer-BioNTech COVID-19 Vaccine. In other clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the vaccine. The vaccine that is authorized for use in children 5 through 11 years of age includes the same mRNA and lipids but different inactive ingredients compared to the vaccine that has been used under EUA in individuals 12 years of age and older and that has been studied in clinical trials. The use of the different inactive ingredients helps stabilize the vaccine under refrigerated temperatures and the formulation can be readily prepared to deliver appropriate doses to the 5 through 11 year-old population.

WHAT ARE THE BENEFITS OF THE VACCINE?

The vaccine has been shown to prevent COVID-19.

The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE VACCINE?

There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, your child's vaccination provider may ask your child to stay at the place where your child received the vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of the face and throat
- A fast heartbeat
- A bad rash all over the body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low. You should seek medical attention right away if your child has any of the following symptoms after receiving the vaccine:

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

Side effects that have been reported with the vaccine include:

- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- myocarditis (inflammation of the heart muscle)
- pericarditis (inflammation of the lining outside the heart)
- injection site pain
- tiredness
- headache
- muscle pain

- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)
- decreased appetite
- diarrhea
- vomiting
- arm pain
- fainting in association with injection of the vaccine

These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If your child experiences a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your child’s healthcare provider if your child has any side effects that bother your child or do not go away.

Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to <https://vaers.hhs.gov/reportevent.html>. Please include “Pfizer-BioNTech COVID-19 Vaccine EUA” in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

You may also be given an option to enroll in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO HAVE MY CHILD GET THE PFIZER-BIONTECH COVID-19 VACCINE?

Under the EUA, there is an option to accept or refuse receiving the vaccine. Should you decide for your child not to receive it, it will not change your child’s standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES PFIZER-BIONTECH COVID-19 VACCINE?

For children 5 through 11 years of age, there are no other COVID-19 vaccines available under Emergency Use Authorization and there are no approved COVID-19 vaccines.

CAN MY CHILD RECEIVE THE PFIZER-BIONTECH COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?

Data have not yet been submitted to FDA on administration of the Pfizer-BioNTech COVID-19 Vaccine at the same time with other vaccines. If you are considering to have your child receive the Pfizer-BioNTech COVID-19 Vaccine with other vaccines, discuss the options with your child’s healthcare provider.

WHAT ABOUT PREGNANCY OR BREASTFEEDING?

If your child is pregnant or breastfeeding, discuss the options with your healthcare provider.

WILL THE VACCINE GIVE MY CHILD COVID-19?

No. The vaccine does not contain SARS-CoV-2 and cannot give your child COVID-19.


KEEP YOUR CHILD’S VACCINATION CARD

When your child gets the first dose, you will get a vaccination card to show when to return for your child’s next dose(s) of the vaccine. Remember to bring the card when your child returns.

ADDITIONAL INFORMATION

If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
<p data-bbox="321 1495 618 1528">www.cvdvaccine.com</p> 	<p data-bbox="932 1570 1198 1640">1-877-829-2619 (1-877-VAX-CO19)</p>

HOW CAN I LEARN MORE?

- Ask the vaccination provider.
- Visit CDC at <https://www.cdc.gov/coronavirus/2019-ncov/index.html>.
- Visit FDA at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.
- Contact your local or state public health department.

WHERE WILL MY CHILD'S VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your child's vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that your child receives the same vaccine when your child returns for the second dose. For more information about IISs visit:

<https://www.cdc.gov/vaccines/programs/iis/about.html>.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?

No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 Uninsured Program for non-insured recipients).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or <https://TIPS.HHS.GOV>.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. An EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based

on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.



Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH

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

LAB-1486-0.3

Revised: 29 October 2021



Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 09/30/2021