



Guidance for The New York State COVID-19 Vaccination Program: Vaccination of Children Ages 5-11

November 4, 2021

Purpose and Background:

On November 2, 2021, following the Food and Drug Administration's emergency use authorization (EUA) on October 29, the Centers for Disease Control and Prevention (CDC) endorsed the CDC's Advisory Committee on Immunization Practices' (ACIP's) recommendation for children ages 5-11 to receive the Pfizer-BioNTech COVID-19 vaccine. This is the first authorized vaccine to be permitted for use in this age group.

All children ages 5 to 11 are now eligible to receive a two-dose primary series of the pediatric formulation Pfizer-BioNTech COVID-19 vaccine, effective immediately. Parents or guardians with questions about the vaccine are encouraged to talk to their child's pediatrician or another trusted healthcare provider.

Note: This document applies specifically to healthcare providers offering COVID-19 vaccinations to children ages 5-11. Guidance for the New York State COVID-19 Vaccination Program pertaining to individuals ages 12 and older can be found on the [New York State COVID-19 Vaccine Information for Providers](#) page.

Important Information about Pfizer-BioNTech COVID-19 Vaccine for Children Ages 5-11:

COVID-19 cases in children can result in hospitalizations, death, MIS-C (an inflammatory syndrome) and other long-term complications in children. Vaccination, along with other mitigation measures, can protect children from COVID-19 using a safe and effective vaccine already recommended for use in adolescents and adults, at a lower dose. The Pfizer-BioNTech COVID-19 vaccine has been shown to be 91% effective in preventing COVID-19 among children ages 5-11. In clinical trials, side effects were mild, self-limiting, and similar to those seen in adults. The most common side effect was a sore arm.

In clinical trials, myocarditis and/or pericarditis have occurred rarely in some people following receipt of mRNA COVID-19 vaccines, typically within a few days following receipt of the second dose. This risk is highest in males ages 12-29 years of age. This risk of myocarditis or pericarditis after receipt of an mRNA COVID-19 vaccine is lower than the risk of myocarditis associated with SARS-CoV-2 infection in adolescents and adults. It is important to clearly describe for parents and guardians the risks of side effects from SARS-CoV-2 infection in children, in addition to the rare risks of the vaccine.

The Pfizer-BioNTech COVID-19 vaccine may be considered for children ages 5-11 with a history of multisystem inflammatory syndrome in children (MIS-C), following careful consideration of risks and benefits. The benefits of COVID-19 vaccination in children and adolescents with a history of MIS-C are likely to outweigh a theoretical risk of an MIS-like illness or the known risks of COVID-19 vaccination for

people who meet all of the following criteria; 1) clinical recovery has been achieved, including return to normal cardiac function; 2) it has been ≥ 90 days since their diagnosis of MIS-C; 3) they are in an area of high or substantial community transmission of SARS-CoV-2; 4) onset of MIS-C occurred before any COVID-19 vaccination.

Data from clinical trials in children 5-11 years old indicate that the Pfizer-BioNTech vaccine can be given safely to those with evidence of prior SARS-CoV-2 infection. Growing epidemiologic evidence from adults and adolescents indicates that vaccination following infection increases protection from subsequent infections, including in the setting of highly infectious variants such as Delta.

Pfizer-BioNTech COVID-19 vaccine pediatric formulation:

The Pfizer-BioNTech vaccine for 5–11-year-olds is a new pediatric formulation (10 μg per dose) with new packaging, new preparation, and a new national drug code (NDC). The current Pfizer vaccine formulation for adults and adolescents (30 μg per dose) CANNOT be used in children ages 5-11 years old. Children ages 5-11 years old should receive the age-appropriate vaccine formulation regardless of their size or weight. The vaccine dosage should be based on the child's age on the day of vaccination. If a child turns from 11 to 12 years of age in between their first and second dose in the primary regimen, they may receive, for either dose, either: (1) the Pfizer-BioNTech COVID-19 Vaccine formulation for children aged 5–11 years (each 0.2 ml dose containing 10 μg in an orange cap vial); or (2) COMIRNATY or the Pfizer-BioNTech COVID-19 Vaccine formulation authorized for use in individuals 12 years of age and older (each 0.3 mL dose containing 30 μg in a purple cap vial). If they receive the 10 μg dose for their second dose instead of the 30 μg dose, this is not considered an error, VAERS reporting is not required, and the child is considered fully vaccinated. However, based on clinical judgment, a repeat dose of the 30 μg adult formulation may be administered 21 days after the second pediatric formulation dose was administered.

The initial packaging configuration will be 10-dose vials in cartons of 30 vials each (300 doses total). The product will be delivered in a newly updated product shipper at -80°C (on dry ice). As of this writing, it is anticipated that the minimum order quantity will shift to 100 doses in the coming weeks (10-vial cartons, rather than 30) – please stay tuned for additional updates from the COVID-19 Vaccination Program for updates on minimum order quantity.

Once the product arrives at the provider site, it can be stored for up to 10 weeks at refrigerated temperatures of 2 to 8°C and up to 6 months at ultra-cold temperatures of -90 to -60°C . No standard freezer storage is approved for the new pediatric formulation. Pediatric vaccine vials do not have expiration dates printed on the label. Instead, the date of manufacture is printed on the label, along with the lot number. The expiration date is currently driven by the beyond use date, which is either six months after manufacture date if stored in ULT or 10 weeks if stored in the refrigerator.

As noted below, responsible wastage policies remain in effect. Providers should plan to minimize waste to the best of their ability but should not miss the opportunity to vaccinate a willing individual, even if it results in other wasted doses.

COVID-19 pediatric vaccines will require diluent. The diluent will be provided with ancillary supplies which are configured specifically for use in children. Reconstitution of the product for use on 5–11-year-olds uses a different volume of diluent than the adult formulation. Please note that once a vial is reconstituted, all 10 doses must be used within 6 hours.

Ordering Instructions:

Please see the [NYSDOH COVID-19 Vaccine Information for Providers](#) page for more information on ordering pediatric Pfizer-BioNTech COVID-19 vaccine in NYSIIS. Providers in New York City should follow instructions from NYC DOHMH and CIR.

Vaccine Provider Responsibilities:¹

- COVID-19 vaccine must be given according to eligibility and criteria established by the ACIP recommendations as well as EUAs and associated fact sheets.
- When managing vaccine inventory, vaccines should always follow a first-in, first-out process in which vials that have the earliest expiration or beyond use date are used first.
- All vaccine providers should minimize the amount of vaccine that goes unused, consistent with CDC guidance, which states that while enrolled providers must continue to follow best practices to use every dose possible, it should not be at the expense of missing an opportunity to vaccinate every eligible person when they are ready to get vaccinated. (See Responsible Wastage section below for further guidance.)
- Providers should not prefill more syringes than they can use within one hour. Prefilled syringes of the Pfizer-BioNTech vaccines must be used within six hours of filling. Excess prefilling can lead to waste if a clinic must end early or an excessive number of recipients fail medical screening or do not show up for their appointment.
- All facilities or practices are required to track vaccine uptake among their staff and must furnish uptake data to the NYSDOH via HERDS survey upon request, or as directed by your agency or organization.

Each provider that receives vaccine:

- Must ensure that parents/guardians of all children receiving the COVID-19 vaccine complete the [New York State COVID-19 Vaccine Form](#) for the first dose, and attest that they are eligible to be vaccinated. All practices, providers, and entities must confirm adherence to this requirement at the time of vaccine administration.
- Must make best efforts to use all vaccine doses before expiration or reaching beyond use dates based on temperature storage requirements by assessing the COVID-19 vaccination status of each patient and offering the vaccine to all eligible individuals. Pediatric vaccine vials do not have expiration dates printed on the label. Instead, the date of manufacture is printed on the label, along with the lot number. The expiration date is currently driven by the beyond use date, which is either six months after manufacture date if stored in ULT or 10 weeks if stored in the refrigerator.

¹ Individuals identified under COVID-19 Public Readiness and Emergency Preparedness Act (PREP Act) declarations are authorized to administer COVID-19 vaccinations in accordance with the PREP Act declaration requirements and subject to any additional guidance or training issued or identified by the New York State Department of Health.

- Providers should continue to report all doses administered to NYSIIS and CIR, including third vaccine doses and booster doses as appropriate based on ACIP recommendations. It is critical that providers follow the appropriate intervals and product combinations in order for these doses to be considered valid. Providers should fully utilize both NYSIIS and CIR to confirm patients' previous dose dates and vaccine type. Full contact information for the parent/guardian of the child receiving the vaccination, including phone number, email and zip code, should be entered as well.

In addition, to ensure all New Yorkers can find vaccination locations close to them, **vaccine providers are strongly encouraged to have their facility/facilities opt-in to the CDC's online VaccineFinder tool ([Vaccines.gov](https://www.vaccines.gov))**. To do so, providers should set the display field in the [COVID-19 Locating Health Portal](#) to "display" if the facility is currently providing vaccinations to the general public. This will allow patients in the local area to see in real-time whether the facility has doses of each brand available, enabling vaccination access for a broader population.

- NYSDOH reports inventory to the CDC every Monday through Friday for each organization. Therefore, organizations do not need to report inventory to VaccineFinder (despite having access).
- Additional information on the VaccineFinder tool can be found [here](#).

Vaccine Redistribution:

Vaccine can be redistributed to another facility, provider, practice, or local health department that is enrolled in the COVID-19 vaccination program, with proper notice to the NYSDOH. Prior to redistributing vaccine, facilities must submit a completed [redistribution form](#) to COVIDVaccineRedistribution@health.ny.gov and can proceed with the redistribution once submitted.

A provider may transport vaccine to another location for the purpose of holding a limited duration vaccination clinic without notifying the NYSDOH. If the provider is administering the doses and reporting doses administered against their own inventory in NYSIIS, all unused vaccine must be transported back to the original location at the conclusion of the clinic that day. The provider must retain possession and control of the vaccine for the duration of the transport and administration.

No Minimum Interval Between COVID-19 Vaccine and Other Vaccines:

The CDC's "[Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States](#)," current recommendations state that "COVID-19 vaccines **may be administered without regard to timing of other vaccines**. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day." Although COVID-19 vaccines were previously recommended to be administered a minimum of 14 days before or after other vaccines, that previous recommendation was out of an abundance of caution and not due to any known safety or immunogenicity concerns and is no longer in effect.

When deciding whether to co-administer another vaccine(s) with COVID-19 vaccines, providers should consider whether the child is behind or at risk of becoming behind on recommended vaccines, their risk of vaccine-preventable disease (e.g., during an outbreak or likelihood of home, school, or extracurricular exposures), and the reactogenicity profile of the vaccines. If multiple vaccines are administered at a

single visit, administer each injection in a different injection site, according to recommendations by age including, but not limited to:

- Consider injection sites separated by 1 inch or more.
- For older children (≥ 11 years old), the deltoid muscle can be used for multiple vaccinations.
- For younger children (5-10 years), if more than 2 vaccines are injected in a single limb, the vastus lateralis muscle of the anterolateral thigh is the preferred site because of the greater muscle mass.

The Second COVID-19 Vaccine Dose:

Pfizer-BioNTech vaccines require two doses. The second dose must be administered 21 days (Pfizer-BioNTech vaccine) after the first dose. To facilitate this, all providers **must** schedule the second dose appointment for recipients **at the time the first dose is administered**.

If a parent requests that their child receive a second dose after missing the 42-day window, a second dose should still be administered. There is no need to restart the series, pursuant to CDC guidance. Providers who have insufficient vaccine to administer a second dose that was delayed beyond the 42-day window should work with their local health department.

Circumstances may arise where a child may need to receive their second dose at a different location than their first. Providers who have determined that the child cannot return to the location where they received their first dose should schedule a second dose for these individuals or coordinate with the local health department to find a provider who has extra doses of the appropriate vaccine to vaccinate the individual. Vaccine availability can also be located using the [CDC's VaccineFinder](#). Individuals should not be tasked with locating second dose appointments. This obligation is on the provider who administered the first dose.

Special Considerations for Individuals Receiving Their First Dose Outside New York State:

Children who received their first dose of COVID-19 vaccine outside of New York State will not have a record of this dose in NYSIIS or CIR. Providers administering a second dose should either enter the first dose in NYSIIS/CIR as part of the historical record using data listed on the child's COVID-19 Vaccination Record Card OR advise the parent that they ask their primary care provider to enter their first dose into NYSIIS/CIR so the state has a full record of both doses of COVID-19 vaccine.

Special Considerations for Individuals Receiving COVID-19 Vaccine Outside the United States:

The [CDC guidance](#) for fully vaccinated people states that "this [CDC] guidance can also be applied to COVID-19 vaccines that have been authorized for emergency use by the World Health Organization (WHO) (e.g., AstraZeneca/Oxford)."

Children who received the first dose of a two-dose mRNA COVID-19 vaccine are not considered fully vaccinated in the United States. They should be offered an age-appropriate second dose of an mRNA vaccine (i.e. Pfizer-BioNTech COVID-19 Vaccine formulation for children ages 5-11).

For COVID-19 vaccines not authorized by the FDA but listed for emergency use by the WHO:

- Children who have received all recommended doses of a COVID-19 vaccine that is listed for emergency use by the WHO **do not need** any additional doses with an FDA-authorized COVID-19 vaccine.
- For children who have not received all the recommended doses of a COVID-19 vaccine listed for emergency use by the WHO, the CDC does NOT consider these persons to be fully vaccinated. They should be offered a two-dose series of the age-appropriate COVID-19 vaccine (i.e. Pfizer-BioNTech COVID-19 Vaccine formulation for children ages 5-11).

For COVID-19 vaccines neither authorized by FDA nor listed for emergency use by the WHO:

- For children who received all or some of the recommended doses of a COVID-19 vaccine that is neither authorized by FDA nor listed for emergency use by the WHO, the CDC does NOT consider these persons to be fully vaccinated. They should be offered a two-dose series of the age-appropriate COVID-19 vaccine (i.e. Pfizer-BioNTech COVID-19 Vaccine formulation for children ages 5-11).

Please note that the minimum interval between receipt of the non-FDA-approved/authorized vaccine and initiation of the FDA-approved/authorized COVID-19 vaccine primary series is at least 28 days.

Responsible Wastage:

The CDC released guidance on May 11, 2021, regarding wastage along with a critical message to “take every opportunity to vaccinate every eligible person.” As more vaccination opportunities are created, the likelihood of leaving unused doses in a vial may increase. While enrolled providers must continue to follow best practices to use every dose possible, it should not be at the expense of missing an opportunity to vaccinate every eligible person when they are ready to get vaccinated.

To ensure providers do not miss an opportunity to vaccinate every eligible person:

- Providers must follow [clinical best practice for vaccination as well as best practices when managing inventory](#) to maximize vaccination and minimize dose wastage.
- Providers should not miss any opportunities to vaccinate every eligible person who presents at a vaccination site.
 - Consider establishing and promoting standing vaccination days or half-days to increase likelihood of larger numbers of people presenting for vaccination on the same day.
 - Vaccinate family members or friends who accompany patients to medical visits even if they are not established patients at the vaccinating practice.
 - Continue outreach to employers or other community partners that have a large membership or network to arrange vaccination events.
 - As contingency plan, vaccine providers should attempt to contact additional persons (i.e., from a standby list or through personal contacts of persons being vaccinated) to use as many vaccine doses as possible.
 - Once punctured, multidose vials of Pfizer-BioNTech must be used within 6 hours.

Vaccine Safety:

Post-vaccination monitoring is an essential part of the COVID-19 vaccination program. The Centers for Disease Control and Prevention (CDC) is promoting and encouraging all those being vaccinated to participate in V-Safe, a smart-phone based application that will allow those vaccinated to enter their symptoms in the days after vaccination using text messaging. V-Safe also provides reminders for the

second dose and telephone follow up for anyone who reports medically significant adverse events. V-Safe materials can be found at <http://www.cdc.gov/vsafe>, including a V-Safe information sheet. Please print out the information sheet and hand to each person vaccinated. You must report any adverse events that occur after vaccination to the Vaccine Adverse Events Reporting System (VAERS) at info@VAERS.org or by calling 1-800-822-7967.

Equity and Access:

Effort must be made to do outreach to families in all communities and settings. Children and families in areas that have a high social vulnerability index are particularly vulnerable to COVID-19 and should be notified about how they can receive vaccine. Every effort should be made to increase their access to vaccination opportunities.

Communicating the Plan:

Please be sure to clearly communicate this critical guidance to all staff involved in the vaccination program.

This guidance is in effect from the date of issuance until it is updated, or additional guidance is issued by NYSDOH. For questions, please contact the New York State Department of Health, Bureau of Immunization at COVID19vaccine@health.ny.gov.

Resources:

- [Vaccine Administration Resource Library for Healthcare Professionals \(CDC\)](#)
- [Epidemiology and Prevention of Vaccine-Preventable Diseases: Vaccine Administration \(CDC\)](#)
- [COVID-19 Vaccine Webinar Series \(CDC\)](#)
- [COVID-19 Vaccination Clinical and Professional Resources \(CDC\)](#)
- [How to Administer Intramuscular and Subcutaneous Vaccine Injections \(Immunization Action Coalition\)](#)
- [Medical Management of Vaccine Reactions in Children and Teens in a Community Setting \(Immunization Action Coalition\)](#)
- [Protective Measures for Vaccinating During the COVID-19 Pandemic \(Immunization Action Coalition\)](#)
- [Skills Checklist for Vaccine Administration \(Immunization Action Coalition\)](#)
- [Supplies You May Need at an Immunization Clinic \(Immunization Action Coalition\)](#)
- [Ask the Experts: COVID-19 Specific Information \(Immunization Action Coalition\)](#)
- [Ask the Experts: Administering Vaccines \(Immunization Action Coalition\)](#)

**New York State COVID-19 Vaccination Program Guidance: Vaccination of Children Ages 5-11
Appendix A**

All individuals 5 years of age and older are eligible to be vaccinated. **However, minors ages 5 through 17 are NOT authorized to receive the Janssen/Johnson & Johnson or Moderna COVID-19 vaccines. They may ONLY receive Pfizer-BioNTech at this time pursuant to the FDA EUA. Children under 5 years of age are not yet authorized to receive ANY COVID-19 vaccine.**

It is important to verify the age of individuals who appear to be a minor to confirm eligibility and ensure the administration of the proper COVID-19 vaccine.

Proof of age should be requested but is not required where the parent or guardian is available to attest to the minor's age. Documentary proof may include (but is not limited to):

- Driver's license or non-driver ID
- Birth certificate issued by a state or local government
- Consulate ID
- Current U.S passport or valid foreign passport
- Permanent resident card
- Certificate of Naturalization or Citizenship
- Life insurance policy with birthdate
- Parent/Guardian attestation

Minor Consent:

16 and 17-year olds:

For all minors, a parent or legal guardian must provide consent for vaccination. For minors 16 or 17 years of age, such consent should be provided either in person or by phone, at the time of vaccine appointment. Providers may elect whether to accept a written statement of consent from the parent or guardian, where the parent or guardian is not available by phone to provide consent to vaccinate an unaccompanied minor. The [NYS COVID-19 Immunization Screening and Consent Form](#) may be considered for this purpose.

5 through 15-year olds:

For minors who are 5 through 15 years of age, additionally, an adult caregiver should accompany the minor. If the adult caregiver is not the parent/guardian, the adult caregiver should be designated by the parent/guardian. The parent/guardian must still provide consent to the vaccination.