

COVID-19 Vaccine Program

Provider Guidance for Pfizer-BioNTech COVID-19 Vaccines for Children Ages 5-11

Ohio's goal is to ensure fair, equitable distribution of the COVID-19 vaccine for younger Ohioans in all 88 counties. With federal review and authorization of the **Pfizer-BioNTech COVID-19 vaccine pediatric formulation for children ages 5-11** now complete, Ohio providers can begin to offer vaccinations as soon as practical.

The U.S. Food and Drug Administration (FDA) has authorized the [emergency use of the Pfizer-BioNTech COVID-19 vaccine pediatric formulation for children ages 5-11](#) following a thorough review of its safety and effectiveness. The Centers for Disease Control and Prevention (CDC) has recommended the vaccine's use, and is expected to offer complete clinical guidance in the near future.

The vaccine for children 5 through 11 years of age is administered as a two-dose primary series, three weeks apart, but is a **lower dose (10 micrograms)** than that used for individuals 12 years of age and older (30 micrograms). The Pfizer-BioNTech COVID-19 vaccine pediatric formulation is a new product configuration with new packaging, new preparation, and a new national drug code (NDC). **The current Pfizer/Comirnaty product for adults and adolescents should not be used in children younger than 12 years old.**

The Ohio Department of Health (ODH) offers the following guidance for providers to administer this new vaccine product for children ages 5-11 and will share updated recommendations and guidance from the CDC as soon as it becomes available.

SUMMARY: COVID-19 VACCINE FOR CHILDREN AGES 5-11

- The Pfizer-BioNTech COVID-19 vaccine pediatric formulation is a new product configuration with new packaging, new preparation, and a new national drug code (NDC). It is a lower dose than the original Pfizer COVID-19 vaccine. ***This product is authorized only for children 5-11 years old.***
- Children ages 12-15 should continue to use the current Pfizer/Comirnaty product for adults and adolescents. ***The original Pfizer COVID-19 vaccine should not be used in children 5-11 years old.***
- The FDA has published emergency use authorization fact sheets for the new **Pfizer-BioNTech COVID-19 vaccine pediatric formulation** for [healthcare providers](#) and for [recipients and caregivers](#). All providers should review this information thoroughly before beginning to administer the vaccines.
- The pediatric formulation will be a two-dose primary series, with the doses given three weeks apart.

- The Pfizer COVID-19 pediatric formulation (orange cap) must be used only for this age group. The current Pfizer COVID-19 adult/adolescent formulation (with a purple cap) cannot be used to vaccinate children ages 5-11 years.
- The pediatric dose contains 10 micrograms (mcg) of the COVID-19 mRNA vaccine (compared with the adult/adolescent dose formulation of 30 mcg of the COVID-19 mRNA vaccine.)
- The injection volume for the pediatric formulation is 0.2 mL (compared with 0.3 mL for the adolescent/adult formulation).
- The preservative-free, multidose vial contains 10 doses.
- It will require [dilution](#) of 1.3 mL normal saline (0.9% sodium chloride preservative-free).
- It will be administered intramuscularly.

STORAGE AND HANDLING

- Temperature storage information is as follows.
 - The product will be shipped in a newly updated ultra-low thermal shipper and may arrive frozen at ultra-cold conditions in thermal containers with dry ice or at -25°C to -15°C (-13°F to 5°F).
 - These shippers are disposable and cannot be used for transport/storage.
 - The vaccine must be unpacked **immediately** and moved to an ultracold freezer OR a refrigerator within five minutes of unpacking.
 - **Ultracold storage units are not required.** If you do not have ultracold storage, plan to order only what you believe can be administered in the first 10 weeks (the maximum time allowed for refrigerator storage).
 - The pediatric vaccine **cannot** be stored in a standard freezer (-25°C to -15°C).
 - Do not refreeze thawed vials.
 - Regardless of storage condition, vaccines should not be used after six months from the date of manufacture printed on the vial and cartons.

Storage Conditions	Temperature	Maximum Storage Time After Arrival at Provider Site
Ultracold (ULT) freezer	-90°C to -60°C	Up to 6 months
Standard freezer	N/A	The pediatric vaccine cannot be stored in a standard freezer.
Refrigerator	2°C to 8°C	Up to 10 weeks

- Once received, frozen vials may be immediately transferred to the refrigerator [2°C to 8° C (35° F to 46° F)], thawed and stored for up to 10 weeks. The 10-week refrigerated expiry date should be recorded on the carton at the time of transfer. A carton of 10 vials may take up to four hours to thaw at this temperature. Alternatively, frozen vials may be stored in an ultra-low temperature freezer at -90° C to -60° C (-130° F to -76° F). Do not store vials at -25°C to -15°C (-13°F to 5°F). Once vials are thawed, they should not be refrozen.

- Once open, doses in vials should be used within 12 hours of dilution. Clinics should consider vial size (10 doses) and a 12-hour time frame when scheduling children for vaccination, especially early in the program, to minimize waste and optimize use of supply.
 - *Vial labels and cartons may state that a vial should be discarded six hours after the first puncture. The information in the [FDA Fact Sheet](#) supersedes the number of hours printed on vial labels and cartons.*
- **Co-administration:** According to the CDC, the Pfizer-BioNTech COVID-19 vaccine pediatric presentation can be co-administered with influenza and routine childhood vaccines. Best practices for administering more than one vaccine, including COVID-19 vaccines and influenza vaccines, include:
 - When preparing more than one vaccine, label each with the name and dosage (amount) of vaccine, lot number, the initials of the preparer, and the exact beyond-use time, if applicable.
 - Always use different injection sites.
 - Separate injection sites by 1 inch or more, if possible, so that any local reactions can be differentiated. Each muscle (deltoid, vastus lateralis) has multiple injection sites.
 - If administered at the same time, COVID-19 vaccines and vaccines that might be more likely to cause a local injection site reaction (for example, Dtap or Tdap vaccines) should be administered in different arms (or legs), if possible.
- Providers should encourage parents or guardians to enroll their children in the [v-safe](#) program to support ongoing vaccine safety monitoring efforts.

ADDITIONAL PEDIATRIC CONSIDERATIONS

- Consent from a parent or guardian is required before youth younger than age 18 years can be vaccinated. Emancipated teens may sign their own consent.
- State law allows those ages 7 years and older to receive a COVID-19 vaccine at a pharmacy. Pharmacists in Ohio may vaccinate children younger than age 7 years if the pharmacist has met certain federal requirements as specified in the [PREP Act](#). The Ohio Department of Health is encouraging Ohioans to check with their pharmacy regarding minimum age for vaccination and availability. More information on state and federal requirements can be found in the following guidance documents from the Ohio Board of Pharmacy:
 - For pharmacists and interns: www.pharmacy.ohio.gov/COVIDvaccine.
 - For qualified techs: www.pharmacy.ohio.gov/TechAdmin.

VACCINE WASTAGE

As vaccine supply, demand, and administration strategies continue to evolve, providers must use new approaches to make vaccine readily available to people in their communities. The Ohio Department of Health recognizes that current vaccine supply, demand, and administration strategies may present an increased risk of vaccine wastage.

Because vaccine must be used in a short time frame once the vial is punctured, best practices should include scheduling appointments whenever possible to help minimize waste. However, providers should also allow the flexibility of walk-ins if possible.

The primary goal should always be to administer COVID-19 vaccines to those who choose to be vaccinated. Vaccine providers should make all reasonable efforts to minimize vaccine wastage and reduce missed opportunities.

VACCINE MANAGEMENT SOLUTION: GETTHESHOT.CORONAVIRUS.OHIO.GOV

Eligible Ohioans will be able to schedule an appointment through Ohio's Vaccine Management Solution (VMS), at gettheshot.coronavirus.ohio.gov. Providers may offer walk-in availability as appropriate.

Providers can now begin offering appointment availability in VMS and are encouraged to offer appointment availability for several weeks out. Providers, in their appointment listings, should also indicate which vaccine products are available at clinics or on an ongoing basis, including the new Pfizer-BioNTech COVID-19 vaccine pediatric formulation for children ages 5-11.

Consent from a parent or guardian is required while scheduling in VMS for youth younger than 18 years. Emancipated teens may sign their own consent.

VMS training materials are available on the [COVID-19 Vaccine Provider VMS Training and Resources page](#).

PLANNING FOR PEDIATRIC FORMULATION ORDERING

- Providers can now order the Pfizer-BioNTech COVID-19 vaccine pediatric formulation. Providers can request vaccine through the Vaccine Ordering Management System (VOMS) in the Impact Statewide Immunization Information System (ImpactSIIS). VOMS is open for providers to place orders 24 hours a day, 7 days a week.
 - Large quantities of Pfizer COVID-19 vaccine formulation shipped directly by the manufacturer:
 - The minimum order is 300 doses, and the maximum order is 600 doses.
 - Ordering is available in the "COVID-19-Pfizer" order set in VOMS.
 - Orders placed the week of Nov. 1 are expected to arrive late the following week, after Nov. 10.
 - In the near future, the direct shipment minimum will be reduced to 100 doses.
 - Small quantities of Pfizer COVID-19 vaccine formulation will be repackaged and shipped by the RSS warehouse:
 - The order quantity is 50 doses.
 - Ordering is available in the "COVID-19-Pfizer 30" or "COVID-19- Pfizer RSS" order sets in VOMS.
 - Delivery will begin Tuesday, Nov. 9, for orders placed by Thursday, Nov. 4, at 6 p.m. In the future, orders will follow the standard Tuesday/Thursday/Friday RSS delivery cadence.
- Only plan to order the Pfizer-BioNTech COVID-19 vaccine pediatric formulation if you will administer pediatric vaccines. Not all providers are expected to administer vaccines to children ages 5-11.
- Smaller providers should plan to form regional partnerships if needed to transfer vaccine during the early distribution phase. If you need assistance with the transfer process, please reach out to the Ohio Department of Health (ODH) Provider Call Center at 1-844-9ODHVAX (1-844-963-4829), available between 8 a.m. and 7 p.m. Mondays through Fridays, or email COVIDVACCINE@odh.ohio.gov.

- Ancillary kits – containing needles, syringes, diluent, alcohol pads, vaccination cards, and surgical masks/face shields for vaccinators – are shipped separately.

HOW TO PLACE AN ORDER IN VOMS

*Note, it may be necessary to reconcile your inventory before ordering. Reconciling **only** your COVID-19 vaccine is acceptable.*

1. Log into your VOMS account.
2. Select your site (if applicable).
3. Click Orders & Returns in the left navigation menu.
4. Click Orders & Transfers.
5. Click New Order.
6. Choose Order Set.
 - Select "COVID-19 Pfizer" order set for direct shipments. After selecting that order set, you will be able to enter a quantity on the line for "COVID-19 Pfizer (300 doses) - Peds" to request Pfizer-BioNTech COVID-19 vaccine pediatric formulation for ages 5-11 years. During the initial phase of ordering, the minimum order quantity is 300 doses.
 - Select "COVID-19 Pfizer 30" or "COVID-19 Pfizer RSS" to order a smaller quantity (50 doses), repackaged by the RSS.
7. Input your order.
 - Enter the total quantity of doses needed in the "Doses Requested" field.
 - **Enter high and low temperatures for your vaccine storage unit in the Comments box.** Pfizer-BioNTech COVID-19 vaccine pediatric formulation orders will need either ultra-cold freezer and/or refrigerator temperatures. Regular freezers are not approved for the Pfizer-BioNTech COVID-19 vaccine pediatric formulation.
 - Enter any additional notes for ODH, such as requests for a special clinic or event. Providers can also use the Comments box for internal notes or reminders for that order.
 - Click Next.
8. Verify your location's shipping address, contact information, and delivery hours. If any information is incorrect, please contact the ODH Immunization Program team at the email address listed below.
9. Click Submit Order.

CONSIDER PARTNERING WITH ANOTHER PROVIDER OR ORGANIZATION

If you are not ready to receive vaccine at your location, consider starting out by building a partnership with other providers or groups in your community, including schools or community organizations supporting youth, for vaccination clinics set up to meet the needs of children.

If you have any questions about enrolling as a COVID-19 vaccination provider, please call the ODH Provider Call Center, available between 8 a.m. and 7 p.m. Monday through Friday at 1-844-9ODHVAX (1-844-963-4829), or email COVIDVACCINE@odh.ohio.gov.

DATA REPORTING

The Ohio Department of Health (ODH) is committed to releasing data to keep the public informed on the COVID-19 pandemic while also protecting the privacy rights of Ohioans. ODH has developed several online data dashboards reflecting information from multiple sources, including vaccination data provided by all enrolled providers.

VACCINE ADMINISTRATION DATA

The [COVID-19 Vaccination Dashboard](#) at coronavirus.ohio.gov displays the most recent data reported to the Ohio Department of Health (ODH) regarding the number of individuals who have started and completed a COVID-19 vaccination series. Data is provided by various demographics and county of residence.

To ensure timely data reporting and sharing, all COVID-19 vaccine providers must report all vaccinations within 24 hours through the [Ohio Impact Statewide Immunization Information System \(ImpactSIIS\)](#).

VACCINE ADMINISTRATION ERRORS AND ADVERSE EVENTS

As part of essential ongoing vaccine safety monitoring efforts, vaccine providers are required to report any adverse events, including vaccine administration errors, to the [Vaccine Adverse Event Reporting System](#).

[VAERS](#) is the nation's early warning system that monitors the safety of vaccines after they are authorized or licensed for use by the FDA. VAERS is part of the larger vaccine safety system in the United States that helps make sure vaccines are safe. The system is co-managed by the CDC and FDA.

VAERS accepts and analyzes reports of possible health problems – also called “adverse events” – after vaccination. If VAERS detects a pattern of adverse events following vaccination, other vaccine safety monitoring systems will conduct follow-up studies.

Visit [VAERS](#) for a complete listing of requirements and step-by-step instructions on how to submit an online report.

MESSAGING

The CDC currently offers tips on [how to talk to parents about COVID-19 vaccines](#) for children and adolescents including:

- Encourage vaccine confidence by being a trusted provider of accurate information. Right now, patients and families may be wading through a lot of information – and misinformation – to make decisions about COVID-19 vaccinations. Consider ways in which patients and families like to receive information and use these mechanisms to debunk common myths and answer frequently asked questions.
- Be prepared to address questions and misinformation about the COVID-19 vaccine with your patients and their parents. The CDC has developed some [useful tips for talking about COVID-19 vaccines](#).
- Share important information including:
 - [Adolescent Vaccines](#) – What parents/guardians need to know when preparing for vaccination for their adolescent child, what to expect during the visit, side effects, and more.
 - [Benefits of Getting a COVID-19 Vaccine](#) – Share the benefits of vaccination with parents and guardians and that it is a safe way to build protection. Getting all eligible family members vaccinated can protect other family members around them.

- [Coadministration of Vaccines](#) – COVID-19 vaccines and other vaccines may now be administered without regard to timing. This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day, as well as coadministration within 14 days.
- [Facts about COVID-19 Vaccines](#) – Accurate information is critical and can help stop common vaccine myths and rumors. This page has information for talking with parents/guardians about common vaccine misconceptions. Reassure parents that there is **no evidence** that any vaccines, including COVID-19 vaccines, can cause female or male fertility problems.
- [V-safe After Vaccination Checker](#) – **V-safe** is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you or your child receive a COVID-19 vaccine.

KEY MESSAGES

- The COVID-19 vaccine for children ages 5-11 years is now available. The vaccine is safe, effective, and has been rigorously tested. Now is the time to get your child vaccinated.
- Topline data for the COVID-19 vaccine for children ages 5-11 years old showed the vaccine was safe and generated robust antibody response.
- The Pfizer-BioNTech vaccine for 5-11-year-olds is a new product configuration of the existing Pfizer-BioNTech COVID-19 vaccine that has been successfully administered to millions of people ages 12 and older across the country. The new pediatric formulation is a lower dose that has been clinically tested for administration in young children.
- Before vaccines can be authorized for use, their safety and effectiveness are thoroughly evaluated by scientists, researchers, medical professionals, the U.S. Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC).
- Messenger RNA (mRNA) technology has been studied for decades.
- The vaccine's safety was studied in approximately 3,100 children 5 to 11 years old who received the vaccine, and no serious side effects have been detected in the ongoing study.
- Pfizer-BioNTech COVID-19 vaccine pediatric formulation for children ages 5 to 11 years was nearly 91% effective at preventing symptomatic infections during clinical trials, and when the Delta variant was widespread. To compare, the flu shot is typically between 40% to 60% effective.
- While children are less likely than adults to get severely ill from COVID-19, they are not invincible. Children most certainly can, and do, become ill. Just like adults, when children become sick from COVID-19, they can spread it to others and suffer severe health outcomes, or even death.
- COVID-19 is a very bad virus, even for children. COVID-19 vaccines provide the best protection and immunity from the disease.
- While severe illness is less common in children, some children can become severely ill, and the longer-term impacts of COVID-19 infection are unknown.
- According to the American Academy of Pediatrics, as of Oct. 28, 2021, [nearly 6.4 million Americans younger than 18](#) had been infected with COVID-19, and CDC data showed that as of Nov. 1, [791 had died](#). In [Ohio](#), nearly 206,000 children have contracted COVID-19, and 15 Ohio residents under age 18 have died.

- Two doses of the Pfizer-BioNTech COVID-19 vaccine pediatric formulation, dosed three weeks apart, will be required for children ages 5-11 years, similar to what is required for older recipients. Full protection is achieved two weeks after the second shot. This means it would take five weeks for your child to achieve full protection. Scheduling an appointment now will ensure your child is protected as soon as possible.
- The side effects from the COVID-19 vaccine, if any, are mild and short in duration. Many people don't experience side effects at all. For those who do, the most common side effects are redness and soreness at the injection site, headache, and fatigue, which typically last one or two days. Side effects are a sign that the vaccine is working and your body is learning to create an immune response.
- Ohioans should choose to be vaccinated regardless of whether they already had COVID-19. Evidence is emerging that people **get better protection by being fully vaccinated** compared with having had COVID-19. [One study](#) showed that unvaccinated people who already had COVID-19 are more than two times as likely than fully vaccinated people to get COVID-19 again.
- Even children who have had, and recovered from, COVID-19 should be vaccinated, if they are eligible. Getting vaccinated is a safer way to build protection than getting infected.
- COVID-19 is still a serious threat to people who are unvaccinated. Some people who get COVID-19 can become severely ill, which could result in hospitalization, and some people have ongoing health problems several weeks after getting infected, or even longer. Even people who did not have symptoms when they were infected can have these ongoing health problems.
- COVID-19 can cause otherwise healthy children to suffer multisystem inflammatory syndrome in children (MIS-C), a potentially life-threatening condition causing inflammation of multiple vital organs. Pediatric hospitals have reported an increase in cases of MIS-C in Ohio.
- Dangerous variants, like the Delta variant, can make children sicker than previous COVID-19 variants, resulting in more children requiring hospitalization.
- Parents worry about rare adverse effects, like myocarditis, an inflammation of the heart muscle. Fortunately, this risk is rare, something most people recover from on their own, and much more likely after being infected with COVID-19 than being vaccinated.

PATIENT MESSAGE TEMPLATE

[Provider name] is now offering COVID-19 vaccines for children ages 5-11 years. These vaccines are safe, effective, and can be administered at the same time as a flu shot or other routine childhood vaccinations. Contact us for more information to give your child the best protection from COVID-19. [Call to action, such as Call XXX-XXX-XXXX or visit www.ourwebsite.com to make an appointment.]

SOCIAL MEDIA POSTS

Following @US_FDA & @CDCgov emergency use authorization, we are now offering #COVID19 vaccines for children 5-11 years old. Learn more about the safety & efficacy of COVID-19 vaccines, so you can make the best decision possible to protect the children in your life. <https://bit.ly/3j7KEc5>

We are now offering #COVID19 vaccines for children 5-11 years old. These vaccines are safe, effective, and can be administered at the same visit as a flu shot or other childhood vaccination. Contact us for more information on protecting your child from COVID-19.

Attention parents: After thorough safety review, the @US_FDA & @CDCgov have granted the Pfizer #COVID19 vaccine for children ages 5-11 emergency use authorization. Schedule your child's vaccination appointment here: gettheshot.coronavirus.ohio.gov

The #COVID19 vaccine is now available for children ages 5-11. The vaccine is safe, effective, and has been rigorously tested. Now is the time to get your child vaccinated. Schedule an appointment here: gettheshot.coronavirus.ohio.gov

The #COVID19 vaccine is now available for children ages 5-11. We know you have questions, and we have answers. The facts show that the vaccine is safe, effective, and has been rigorously tested. Learn more about #COVID19 vaccines for children in our #FAQ at <https://coronavirus.ohio.gov/static/vaccine/youth-vaccines-faq.pdf>.

Now that the #COVID19 vaccine is available for kids 5-11, you may be wondering where your child can get vaccinated. Many hospitals, pharmacies, health departments and some pediatricians are booking appointments. Find a provider near you gettheshot.coronavirus.ohio.gov

Updated Nov. 2, 2021.

For additional information, visit coronavirus.ohio.gov.

The [Ohio Department of Health COVID-19 Provider website](#) is a hub for a variety of resources for vaccine providers. Vaccine providers with questions may call the ODH Provider Call Center at 1-844-9ODHVAX (1-844-963-4829) between 8 a.m. and 7 p.m. Mondays through Fridays or email COVIDVACCINE@odh.ohio.gov.