



Department  
of Health

Mike DeWine, Governor  
Jon Husted, Lt. Governor

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Feb. 8, 2022

To All Enrolled COVID-19 Vaccine Providers,

For a limited time, vaccine providers who plan to administer COVID-19 vaccines to **children ages 6 months through 4 years** – following federal authorization of Pfizer-BioNTech’s new product for young children – can place advance orders for the vaccine. This advance ordering window allows providers the chance to be among the first recipients of the new formulation created for this age group. *The vaccine can be shipped following U.S. Food and Drug Administration (FDA) emergency use authorization; however, doses cannot be administered until the Centers for Disease Control and Prevention (CDC) makes a recommendation.*

Ordering is now open through the ImpactSIIS Vaccine Ordering Management System (VOMS), and orders for this initial ordering window must be submitted no later than **noon on Thursday, Feb. 10, 2022**. It’s important to note that any providers placing orders for this first set of deliveries must have staff available to receive the shipment on President’s Day, Monday, Feb. 21.

**The current Pfizer products for adults, adolescents, and children ages 5-11 years should NOT be used in children ages 6 months to 4 years.** The Pfizer-BioNTech vaccine for ages 6 months to 4 years will be a new product configuration with new packaging and a new national drug code.

#### **Next steps: Federal review/approval**

The FDA’s Vaccines and Related Biological Products Advisory Committee (VRBPAC) is scheduled to meet to review Pfizer’s application for emergency use authorization for this formulation for young children on Feb. 15. The full FDA would act after reviewing the panel’s recommendation. Then, the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices (ACIP) would convene following FDA action. The CDC director would issue the final recommendation following a review of ACIP’s recommendation.

Providers should be ready to vaccinate children ages 6 months to 4 years old shortly thereafter, pending FDA authorization and CDC recommendations.

## Vaccine ordering

- VOMS is open for providers to place orders 24 hours a day, 7 days a week.
- Orders for the first round of deliveries starting on Feb. 21 must be submitted in VOMS no later than **noon on Thursday, Feb. 10, 2022.**
- Orders can be placed using the existing **COVID-19 – Pfizer order set**, with a minimum order of 100 doses. The new formulation for 6 months to 4 years (maroon cap) will be one of three options under this order set. Providers would enter the quantity requested in the Doses Requested field.
- **For initial orders of this Pfizer product, the new pediatric formulation must be the only product requested in the order. A separate order** will need to be created for providers who also want doses of a different Pfizer formulation or another COVID-19 vaccine product.
- The ability to use all 10 doses within 12 hours once a vial is opened should be a planning consideration for initial orders. Sites should consider currently configured vial size (10-dose vials) in planning when scheduling children for vaccination, especially early in the program, to optimize use of supply.
- While it is highly recommended to plan to order early to ensure you are among the first to be able to provide the new pediatric formulation (ages 6 months to 4 years) following authorization, there will also be future opportunities to order vaccine.
- **A second window for ordering will begin Feb. 11**, with those deliveries beginning as early as Feb. 22, pending FDA authorization. As with all COVID-19 vaccine products, providers are encouraged to order lean and as often as needed to meet vaccine inventory needs and avoid waste.

## Product highlights

Preliminary product information, pending FDA authorization, is as follows.

- The Pfizer-BioNTech vaccine for children 6 months to 4 years will be a new product configuration with new packaging and a new national drug code (NDC).
- The current adult/adolescent formulation (with a purple or grey cap) cannot be used to vaccinate children younger than age 12. The pediatric (orange cap) formulation cannot be used to vaccinate children younger than age 5 or older than age 11. The new pediatric 6 months to 4 years (maroon cap) formulation cannot be used in people older than age 4 or younger than 6 months.
- Preliminary information suggests the new pediatric formulation will:
  - Come in a vial with a maroon cap.
  - Require dilution.

- Have dosage of 3 micrograms/0.2 mL and 2.2mL diluent.
- Contain 10 doses per vial and 10 vials per carton for a total of 100 doses.
- Ancillary kits will support 100 doses.
- The product will be delivered in a product shipper at minus 80 degrees Celsius. You do not need ultracold storage units to order this vaccine. If you do not have ultracold storage, plan to order only what you believe can be administered in the first 10 weeks following FDA authorization.

<b>Storage Conditions</b>	<b>Temperature</b>	<b>Maximum Storage Time After Arrival at Provider Site</b>
Ultracold (ULT) freezer	-90°C to -60°C	Up to 9 months
Refrigerator	2°C to 8°C	Up to 10 weeks

The Ohio Department of Health will continue to share updates and resources as we learn more about this new COVID-19 vaccine product. Thank you for your continued partnership in vaccinating Ohioans.

*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 5:30 p.m. Mondays through Fridays or email [COVIDVACCINE@odh.ohio.gov](mailto:COVIDVACCINE@odh.ohio.gov).*

Sincerely,

Ohio COVID-19 Vaccine Provider Relations Team