

Vaccine Ordering Guidance for Pfizer Age 5 through 11 Years

Overview: Allocations are being applied nationally for the new pediatric Pfizer COVID-19 vaccine for ages 5 through 11 years. A pre-order period will occur prior to EUA issuance to ensure timely and efficient distribution. This pre-order period will consist of three 48-hour waves, from October 20th to October 26th.

Following the pre-order period, CDC will apply allocations on a weekly cadence. CDC reports a strong supply of this product. For Michigan COVID-19 Vaccine Providers, ordering will occur in the MCIR E-Ordering system, aligning with the process for current COVID-19 vaccine orders and aligning with the method that is used by our Vaccines for Children (VFC) Program Providers. MDHHS and Local Health Departments will oversee the ordering and distribution process to ensure equitable access to the vaccine.

ALLOCATION & ORDERING TIMELINE

PRE-ORDERS

Pre-Orders will be placed by providers and reviewed/approved/revised by Local Health Departments. They are then batched up and submitted to CDC by MDHHS. There will be 3 “waves” of pre-orders beginning on October 20th. Please note the timeframes below for each wave and that each wave corresponds will a different “Delivery timeframe”.

Once a wave ends OR a pre-order cap has been met, the product will be turned off and not available for E-ordering. It will then be turned back on once the next wave begins. If there is un-used vaccine in a wave, it will roll over to the next.

Providers requesting orders of this product must be confident in using the minimum order quantity:

- 300 dose minimum orders during the pre-order launch (10/22 – 10/26)
- Following the pre-launch period, minimum dose orders will be 100 doses
- Vaccine may be available in smaller quantities from your Local Health Department. This route should be utilized for sites that cannot utilize minimum order quantities.

Total Pre-Order Allocation: **287,700 doses total, which will be available in 3 waves as shown below.**

1. Pre-Order Wave 1 - October 20th – October 22nd

- **Allocation: 114,900 doses**
- **Order timeframe: 10/20 at 9:30am to 10/22 at 8:00am**
 - The orders must **be at the MDHHS level** within this timeframe (approved by the LHD). At the end of the timeframe (8:00am), MDHHS batches orders for submission to CDC.
- Delivery timeframe: Some Wave 1 orders will deliver the next day following EUA issuance. Wave 1 orders will deliver between one (1) and five (5) business days after EUA issuance.

2. Pre-Order Wave 2 - October 22nd – October 24th

- **Allocation: 86,400 doses**
- **Order timeframe: 10/22 at 9:30am to 10/24 at 8:00am**
 - The orders must **be at the MDHHS level** within this timeframe (approved by the LHD). At the end of the timeframe (8:00am), MDHHS batches orders for submission to CDC.
- Delivery timeframe: Wave 2 deliveries will commence immediately after Wave 1 deliveries are processed. It is possible that some early Wave 2 deliveries may be made on the same

day as final Wave 1 deliveries. Wave 2 orders will deliver three (2) to seven (7) days after EUA issuance.

3. Pre-Order Wave 3 - October 24th – October 26th

- Allocation: 86,400 doses
- Order timeframe: 10/24 at 9:30am to 10/26 at 8:00am
 - The orders must **be at the MDHHS level** within this timeframe (approved by the LHD). At the end of the timeframe (8:00am), MDHHS batches orders for submission to CDC.
- Delivery timeframe: Wave 3 deliveries will commence immediately after Wave 2 deliveries complete. It is possible that some early Wave 3 deliveries may be made on the same day as final Wave 2 deliveries. Wave 3 orders will deliver five (5) to nine (9) days after EUA issuance.

In order to maximize delivery of pediatric doses, during this launch, **ordering of ADULT/ADOLESCENT Pfizer (product for 12 years+) will be paused at 2pm on Thursday October 29th. This refers to the time when the order needs to be at the MDHHS level. Ordering will restart on Thursday November 4th.**

AFTER PRE-ORDERS

- Following pre-order waves, CDC indicates allocations will be weekly
- More information will be shared as it becomes available

ORDERING PROCESS

COVID-19 Providers will place orders (pre-orders and orders) using the current ordering methodology for COVID-19 vaccines – using the MCIR to place E-Orders.

- E-Orders are reviewed by the Local Health Department, approved/revise if appropriate, and submitted to MDHHS. MDHHS batches orders daily for submission to CDC. Guidance, a webinar, and tip sheets are available to instruct on the E-Ordering Process for COVID-19 Vaccine (www.Michigan.gov/COVIDVaccineProvider).
- MDHHS will use CDC-provided allocations to set caps in the E-Order system.
- This new Pfizer 5-11 year-old product will be added to the E-Order system in MCIR. This is anticipated to be live on October 20th.
- Once a wave ends OR a pre-order cap has been met, the product will be turned off and not available for E-ordering. It will then be turned back on once the next wave begins. If there is unused vaccine in a wave, it will roll over to the next.
- **Important note when ordering:** Please pay attention to product descriptions to differentiate from the adult/adolescent product. **This new product for ages 5-11 years has an NDC of 59267-1055-04, a dosage of 10mcg and is displayed as follows:**

59267-1055-04	COVID-19 PFR-BTN 10/CTN (Pfizer) SARS-COV-2 (COVID-19) vaccine, mRNA, LNP-S, PF, 10 mcg/0.2 mL dose, tris-sucrose	CTN	300	Add to Order
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- It also has the order QTY as 300-dose minimum (order increments of 300). Following the pre-order launch, this will be updated to 100-dose order minimums and increments.

- **Order Quantities:** For pre-orders (first week of order launch), the minimum order quantity will be 300 doses per order. More than 300 doses may be ordered in 300-dose increments (300, 600, 900, etc.). Following the pre-order period, the minimum order quantity will be 100 doses.
 - These minimum order quantities will be reflected in the E-Order system
- When placing orders, please be mindful and responsible to ensure that you are placing orders **with the knowledge that additional vaccine will be made available each week**. CDC reports a strong supply. Avoid placing orders for excessive doses of vaccine. Keep in mind storage capabilities, populations served, etc. Orders may be revised prior to approval if necessary.
- **Review/approval of orders will be based on the following:**
 - Providers able to use the minimum order quantities:
 - 300 doses in the first week (pre-orders) and 100 doses in the following weeks
 - Providers with appropriate storage (refrigeration storage unit or ultra-cold storage unit)
 - Refrigerated doses must be used within 10 weeks
 - Ultra-cold doses must be used within 6 months
 - Providers who vaccinate pediatric populations and an emphasis on ensuring support for providers that see vulnerable populations (e.g., pediatric clinics, federally qualified health centers, health departments, school-based health centers, rural health clinics, etc.)
 - Including Vaccines for Children (VFC) Providers enrolled as COVID-19 Providers
 - All LHD jurisdictions are expected to place orders to ensure access across the state
 - LHDs are not only key to vaccinating this population but also have the ability to redistribute/transport smaller vaccine quantities to providers unable to use the minimum order quantity
 - Order quantities may be revised to ensure equitable distribution
 - If areas of low distribution are observed, outreach will occur to inform Local Health Department Immunization Leads and Immunization Field Representatives in that area to increase provider engagement and ordering
 - **Federal entity and pharmacy channels:**
 - **Important note regarding FQHCs and RHCs:** These entities may utilize our state allocation and E-Ordering **during the pre-order period**. Please review these E-Order requests appropriately as they are an important partner in ensuring equitable access of this vaccine to children. **AFTER pre-orders**, they will have access to place orders through their HRSA ordering method. Therefore, E-Order requests from these sites should not be excessive.
 - Pharmacies participating in the Federal Retail Pharmacy Program (FRPP), DOD, DHS, IHS will be able to order vaccine through direct allocations.
- Second doses
 - 21-day interval is assumed as of 10/18 (to be confirmed upon EUA)
 - CDC nor MDHHS will “hold back” doses specified as second doses. Providers are responsible to order vaccine and manage inventory appropriately to ensure second doses are provided at the appropriate time.
 - CDC reports confidence in supply

COMMUNICATION

- Guidance on HOW to order is available on our COVID-19 Vaccine Provider website (www.Michigan.gov/COVIDVaccineProvider).

- Order emails are sent by Pfizer when shipment occurs (with tracking #)
- Emails are sent by MCIR upon order approval and upon shipment

Reminder on timeline for VRBPAC and ACIP:

- FDA's Vaccines and Related Biological Products Advisory Committee is scheduled to meet October 26th to discuss Pfizer's submission for vaccines for 5-11 year old children.
- CDC's Advisory Committee on Immunization Practices is scheduled to meet November 2-3.
 - Vaccinations for 5–11-year-olds would not begin until after CDC makes a recommendation for use, consistent with requirements in the provider agreement.