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Sent: Thursday, September 29, 2022 1:38 PM

Subject: New Pediatric Bivalent Booster Coming Soon, Pre-order Your Vaccine Now



## **September 29, 2022**

This communication is being sent to all key contacts at provider organizations administering COVID-19 vaccine— please read this message in its entirety. Please feel free to share it with others in your organization who may benefit from the update. Note that all our communications are archived on our web site.

Dear Connecticut COVID-19 Vaccine Providers,

Both <u>Pfizer</u> and <u>Moderna</u> have filed an Emergency Use Authorization (EUA) for its updated bivalent COVID-19 vaccine for use in children. The FDA is expected to issue an EUA the week of October 10<sup>th</sup> and the CDC director is expected to endorse an official recommendation the same day. Pfizer pre-orders will begin shipping once an EUA is issued.

Please read the product information below before placing an order:

- The updated bivalent COVID-19 vaccines will only be authorized as a single booster dose in children who have completed an age-appropriate primary vaccination series.
- Additional details, such as interval from primary series completion to the bivalent booster dose, will be available after the EUA is issued. We will share those details once we have them.
- Pfizer will have a NEW product for children aged 5-11 years.
  - New product with a new NDC.
  - Packaging: 10-dose vials in cartons of 10 vials each (100 doses total), with minimum order quantity of 100 doses for direct shipment. All other orders will be delivered by redistribution.
  - Vial will have an orange cap, like the currently existing monovalent pediatric product, but will have a label saying it is a bivalent product.
  - o Will require a diluent that ships with the ancillary kit. (no ancillary kit opt out)
  - The new vaccine will have the same storage and handling parameters as the adult <u>Pfizer vaccine product</u>.
    - Ultra-cold freezer storage (-90°C to -60°C) until expiry
    - NO FREEZER STORAGE
    - Refrigerate (2°C to 8°C) up to 10 weeks without puncturing
    - Once punctured, each vial must be used within 12 hours
- Moderna will use the SAME product as adults for children aged 6-17 years, but with different dosing.
  - There is no new product or NDC; the current updated adult Moderna bivalent vaccine can be used for children 6-17 years.
  - The vial has a dark blue cap with a grey boarder. The same vial is used for all age groups, only the dose amount differs.

- Children aged 12-17: same dose as an adult (0.5mL)
- Children aged 6-11 years: half the volume as the adult dose (0.25mL) drawn from the same vial
- Packaging: 5-dose vials in cartons of 10 vials each (50 doses total), with minimum order quantity of 100 doses for direct shipment. All other orders will be delivered by redistribution.
- No diluent required. Providers can opt out of ancillary kits for this
  product. Additionally, if providers indicated that they are ordering this vaccine for
  children aged 6-11 they will get double the ancillary kits to accommodate the
  dosing.
- The new vaccine will have the same storage and handling parameters as the original <u>Moderna vaccine products</u>.
  - NO ULTRA-COLD FREEZER STORAGE
  - Freezer storage (-50°C to -15°C) until expiry
  - Refrigirate (2°C to 8°C) up to 30 days without puncturing
  - Once punctured, each vial must be used within 12 hours

## **Placing Orders**

In anticipation of this age expansion, the Department of Public Health Immunization Program is accepting pre-orders for the new updated pediatric bivalent Pfizer booster formulation and orders for the current updated bivalent Moderna vaccine.

The Pfizer pre-orders will be shipped once the EUA is issued and are anticipated to arrive as early as the week of October 10<sup>th</sup>. The Moderna orders will be placed after the order deadline and arrive the following week. Providers must wait to administer the updated bivalent Moderna vaccine to children 6-17 years of age until CDC endorses an official recommendation.

Please note that at this time allocation of the updated bivalent Moderna vaccine are still limited and providers should consider using the updated bivalent Pfizer vaccine instead, to ensure that there are no delays or disruption of vaccine to your clinic.

For delivery during week 1 of distribution, please complete this pre-order form by noon Tuesday October 4<sup>th</sup>. Weekly ordering will be established through the ordering portal after the EUA is issued.

## **Additional Updates**

The public will be directed to <u>Vaccines.gov</u> to find providers offering bivalent COVID-19 vaccine. After receiving your initial vaccine orders, providers are asked to report their inventory to Vaccines.gov as soon as possible.

Providers are strongly encouraged to adopt strategies to minimize unnecessary vaccine wastage, however, they should not miss any opportunities to vaccinate every eligible person who requests a vaccination, even if it means puncturing a multidose vial to administer vaccine without having enough people available to receive each dose in the vial.

In order to continue offering primary series vaccines in addition to bivalent boosters, providers will need to keep multiple COVID-19 vaccine products in their inventory throughout the fall. CDC recommends providers offer simultaneous administration of all age-appropriate doses of vaccines for children, adolescents, and adults for whom no contraindications exist at the time of the healthcare visit.

## Thank you for all your ongoing work and support of our COVID-19 vaccine roll-out in Connecticut.

For the CT DPH Immunization Program, visit: Contact Us
For the COVID-19 webpage, visit: COVID-19 Vaccine Program

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