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**Sent:** Wednesday, November 30, 2022 10:16 AM

**Subject:** New (Under 5/6) Pediatric Bivalent Booster Coming Soon, Pre-order Your Vaccine Now



DEPARTMENT OF PUBLIC HEALTH

**November 30, 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,

If authorized by the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC) anticipates a recommendation for bivalent COVID-19 vaccine for additional pediatric age groups **in mid-December**. Bivalent COVID-19 vaccine products expected to be under consideration in December include the bivalent Pfizer-BioNTech vaccine for children aged 6 months through 4 years and bivalent Moderna vaccine for children aged 6 months through 5 years. The Connecticut Immunization Program will now be accepting pre-orders for these vaccines in anticipation of the recommendation. **Pre-orders placed by December 5<sup>th</sup> will begin shipping once an EUA is issued.**

Please read the planning assumptions below before placing an order:

- At this time, it is expected that children in these age groups will be required to receive two doses of monovalent (original composition) COVID-19 vaccine before receiving a dose of bivalent (new composition) COVID-19 vaccine. Since Moderna's bivalent COVID-19 vaccine is expected to be authorized as a booster, and Pfizer-BioNTech's is expected to be authorized as part of the pediatric primary series, mix-and-match use is NOT expected to be authorized.
- It is expected that children aged 6 months through 4 years who received two doses of monovalent Pfizer-BioNTech COVID-19 vaccine will be authorized to receive a third dose of bivalent vaccine to complete their primary series. Children who received one dose of monovalent Pfizer-BioNTech COVID-19 vaccine would need to receive a second dose of monovalent Pfizer-BioNTech COVID-19 vaccine before receiving a dose of bivalent Pfizer-BioNTech COVID-19 vaccine. It is expected that children aged 6 months through 4 years who received three doses of monovalent Pfizer-BioNTech COVID-19 vaccine to complete their primary series will not be authorized to receive a booster dose of bivalent COVID-19 vaccine at this time.
- It is expected that children aged 6 months through 5 years who received one dose of monovalent Moderna COVID-19 vaccine will need to receive a second dose of monovalent Moderna COVID-19 vaccine to complete their primary series before receiving a bivalent Moderna COVID-19 vaccine dose as a booster. (Children 5 years of age who completed the monovalent Moderna primary series are currently authorized to receive a bivalent Pfizer-BioNTech booster.)

- [CDC IIS Data Code Sets](#) provides the current immunization information system (IIS) codes and crosswalks to ensure your electronic health record (EHR) system is updated with the current code sets.

**TIP:** Enter your email address on the CDC web page to receive updates. This will help you keep your EHR system updated to ensure accurate and complete reporting to CT WiZ.

- **Pfizer-BioNTech COVID-19 Vaccines** (expected characteristics of Pfizer-BioNTech bivalent COVID-19 vaccine for children aged 6 months through 4 years):
  - Will be a new product with a new NDC
  - New product will have the same storage and handling parameters as the other [Pfizer COVID-19 vaccine products](#). (Ultra-cold freezer storage (-90°C to -60°C) until expiry; NO FREEZER STORAGE (-25°C to -15°C); if unpunctured, may be refrigerated (2°C to 8°C) for up to 10 weeks; once punctured, each vial must be used within 12 hours)
  - Requires 2.2 mL diluent per vial; diluent that ships with the ancillary kit (no ancillary kit opt out); Dose 3mcg/0.2mL
  - Packaged in 10-dose vials in cartons of 10 vials each (100 doses total); minimum order quantity of 100 doses for direct shipment. All other orders will be delivered by redistribution.
  - Maroon cap identical to the monovalent Pfizer-BioNTech product for this age group
  - New label identifying the product as a bivalent vaccine (i.e., Original and Omicron BA.4/BA.5)
- **Moderna COVID-19 Vaccines** (expected characteristics of Moderna bivalent COVID-19 vaccine for children aged 6 months through 5 years):
  - Will be a new product with a new NDC
  - The new vaccine will have the same storage and handling parameters as the original [Moderna vaccine products](#). (Freezer storage (-50°C to -15°C) until expiry; if unpunctured, may be refrigerated (2°C to 8°C) up to 30 days; once punctured, each vial must be used within 8 hours)
  - Does not require diluent; dose 10mcg/0.2mL
  - Packaged in 2-dose vials in cartons of 10 vials each (20 doses total)
  - Vial with dark pink cap and yellow border on the label

## Placing Orders

**Providers must wait to administer the updated bivalent vaccine to children under 5/6 years of age until CDC endorses an official recommendation.**

Please note that at this time allocation of the updated bivalent vaccines for this age group are still limited and orders for product will be honored based on available supply.

**For delivery during week 1 of distribution, please complete a pre-order in the [COVID-19 Vaccine Ordering Portal](#) by noon Monday December 5<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 [Vaccines.gov](#) 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.

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.

### **Reminder: Expiration Dates and Shelf-life Extensions**

Recently monovalent Moderna10 products were given a shelf-life extension. There were 12 lots that were updated with expiration dates in February 2023. See the list below.

<b>Count</b>	<b>Lot #</b>	<b>OLD Expiry (9-month from DOM)</b>	<b>New Expiry (verified)</b>
1	054A22A	2022-11-01	Feb 1, 2023
2	055A22A	2022-11-02	Feb 2, 2023
3	057A22A	2022-11-06	Feb 6, 2023
4	056A22A	2022-11-07	Feb 7, 2023
5	059A22A	2022-11-09	Feb 9, 2023
6	058A22-2A	2022-11-10	Feb 10, 2023
7	060A22A	2022-11-10	Feb 10, 2023
8	014B22A	2022-11-11	Feb 11, 2023
9	015B22A	2022-11-12	Feb 12, 2023
10	016B22A	2022-11-13	Feb 13, 2023
11	017B22A	2022-11-14	Feb 14, 2023
12	011B22A	2022-11-18	Feb 18, 2023

We encourage providers to:

- Monitor expiration dates weekly, rotate stock as needed, and follow a “first in, first out” strategy to manage inventory.
- If nearing expiration, check posted manufacturer information for the most up to date expiration/extension information for vaccine lots.
  - **Pfizer:** <https://lotexpiry.cvdvaccine.com>
  - **Moderna:** <https://modernacovid19global.com/vial-lookup>
  - **Novavax:** <https://us.novavaxcovidvaccine.com/hcp>
  - **Johnson and Johnson/Janssen:** <https://vaxcheck.jnj/>
- Based on the latest expiration information, REMOVE expired vaccine from the storage unit IMMEDIATELY. Do not give staff opportunity to administer expired vaccine.

If expired vaccine is inadvertently administered, it is considered a vaccine administration error and requires remediation including a VAERS report, contacting the recipient to inform them of the error, and may or may not require revaccination based on the manufacturers’ guidance. Guidance on vaccine administration errors can be found in Appendix A of the [Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States](#).

Vaccine disposal: dispose of the vaccine vial (with any remaining vaccine) and packaging as medical waste. Do NOT return vaccine in the thermal shipping container.

Report expired and wasted vaccine

- Please promptly report any expired and/or wasted vaccine to the CT WiZ [Helpdesk](#). Keep in mind that there are no negative consequences for reporting waste, and it will not negatively impact future vaccine orders.

**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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