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Sent: Wednesday, October 12, 2022 2:18 PM

Subject: CDC Recommends Updated Bivalent Booster for Everyone Age 5 and older



## October 12, 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,

Today the FDA expanded the age authorization for both Moderna and Pfizer-BioNTech bivalent boosters. The Centers for Disease Control and Prevention (CDC) is now recommending that everyone aged 5 and older receive one dose of the updated bivalent booster.

## Moderna bivalent

- Individuals 6 years of age and older are eligible for a single booster dose of the Moderna bivalent COVID-19 vaccine if it has been at least two months since they have completed primary vaccination or have received the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.
- Vaccine for expanded ages is identical to the current adult Moderna Bivalent Vaccine. There is no new NDC.
  - Packaging: 5-dose vials in cartons of 10 vials each (50 doses total)
  - No diluent required
  - Vial has a dark blue cap with a grey boarder, like the currently existing bivalent Moderna product. The same vial is used for all age groups, only the dose amount differs
  - Children aged 12 17 years: administer the same dose/volume as you would an adult
  - Children aged 6 11 years: administer half the dose/volume as the adult dose
  - Storage conditions are identical to the adult product and vials must be used within 12 hours after puncturing

## Pfizer bivalent

- Individuals 5 years of age and older are eligible for a single booster dose of the Pfizer-BioNTech bivalent COVID-19 vaccine if it has been at least two months since they have completed primary vaccination or have received the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.
- New product for children aged 5 11 years with a new NDC.

- Packaging: 10-dose vials in cartons of 10 vials each (100 doses total)
- o Requires a diluent in the ancillary kit
- Vial has an orange cap, like the currently existing monovalent pediatric product, but will have a label saying it is a bivalent product
- Storage conditions are identical to the adult product and vials must be used within 12 hours after puncturing

The recommendation was simplified in September and if eligible (see table below), a bivalent booster should not be denied based on total number of doses.

Vaccination history	<b>—</b>	Next dose
Primary series	At least 2 months	1 bivalent booster dose
Primary series + 1 booster	At least 2 months	1 bivalent booster dose
Primary series + 2 booster	At least 2 months	1 bivalent booster dose

<u>Interim Clinical Considerations</u> for healthcare providers have been updated and other <u>associated materials</u> will be updated shortly.

COVID-19 vaccine providers in Connecticut may begin administration of doses in line with the FDA emergency use authorization and CDC recommendations as soon the vaccine arrives.

Providers can order both the Moderna and Pfizer bivalent vaccines using the standard weekly ordering practice through the <u>submissions portal</u>.

- 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; this includes influenza vaccines.
- Pfizer has virtual training for providers on their new COVID-19 bivalent booster vaccine as a booster dose in individuals 12 years of age and older; to access dates and links for upcoming training sessions, visit the Pfizer website.
- Moderna has a virtual educational webinar and interactive office hours for providers on their new COVID-19 bivalent booster vaccine; to see webinar dates and register click <u>here</u> and to see office hour times click <u>here</u>.

## Use of Current Monovalent\* mRNA COVID-19 Vaccines

(\* Monovalent mRNA COVID-19 Vaccines are the initial Moderna and Pfizer products that contain the original strain only.)

With today's authorization, the monovalent Pfizer-BioNTech COVID-19 Vaccine is no longer authorized as a booster dose for individuals five through 11 years of age. Both the Moderna COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine continue to be authorized for primary series administration in individuals six months of age and older. This change is NOT due to any safety concerns, but rather in anticipation of improved effectiveness of the new bivalent mRNA vaccines. Providers should do the following:

- Providers should not discard any monovalent mRNA COVID-19 vaccine that they
  currently have in inventory. They should continue to properly store and handle these
  vaccines until expiration or until further direction is provided.
- The monovalent mRNA COVID-19 vaccine is still safe and effective and should be administered for the primary series in individuals 6 months and older.
- Appointments for monovalent Pfizer-BioNTech or Moderna boosters in people 5
  years of age and older must be rescheduled for when locations have the ageappropriate bivalent COVID-19 vaccines available.

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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