December 14, 2022

Dear Colleague,

The Centers for Disease Control and Prevention (CDC) has expanded the use of bivalent COVID-19 vaccines to children ages 6 months through 5 years. The changes follow Emergency Use Authorizations (EUAs) from the U.S. Food and Drug Administration for the following products:

- The <u>bivalent Moderna booster for ages 6 months through 5 years</u> (dark pink-capped vial with yellow-bordered label) is packaged in two-dose vials. These are NOT single-dose vials. The dosage/injection volume for each booster dose is 10 mcg/0.2 mL. If a whole vial of this vaccine is inadvertently administered, it is a vaccine administration error and should be reported to <u>Vaccine Adverse Event Reporting System (VAERS)</u>.
- The <u>bivalent Pfizer vaccine for ages 6 months through 4 years</u> (maroon cap and label border) is packaged in 10-dose vials. The dosage/injection volume for each dose is 3 mcg/0.2 mL. The EUA fact sheet has been updated to include both the monovalent and bivalent Pfizer products for children ages 6 months through 4 years in a single fact sheet.

The updated recommendations are reflected in the CDC's Clinical Considerations:

- Children ages 6 months through 4 years who complete a Moderna primary series are recommended to receive one bivalent Moderna booster dose at least 2 months after completion of the primary series. Heterologous booster doses for this age group are not authorized at this time.
- Children age 5 years who complete a Moderna primary series may receive either the
 previously authorized bivalent Pfizer booster dose for ages 5 through 11 years (10
 mcg/0.2 mL) or the newly authorized bivalent Moderna booster dose for ages 6 months
 through 5 years (10 mcg/0.2 mL) at least 2 months after completion of the Moderna
 primary series.
- Children age 5 years who complete a Pfizer primary series are recommended to receive a previously authorized Pfizer bivalent booster dose for ages 5 through 11 years (10 mcg/0.2 mL); these children cannot receive a bivalent Moderna booster.
- The previously authorized three-dose Pfizer primary series for children ages 6 months through 4 years has been revised as follows: a monovalent Pfizer vaccine is administered for the first and second doses, followed by one <u>bivalent</u> Pfizer vaccine as the third primary series dose, at least 8 weeks after the second monovalent primary series dose. A heterologous third dose is not authorized at this time (i.e., these children cannot receive Moderna bivalent vaccine for the third primary series dose).
 - At this time, booster doses are not authorized for children ages 6 months through 4 years who receive a Pfizer three-dose primary series, including children who previously received a three-dose monovalent Pfizer primary series.

CDC has released <u>guidance for special situations</u> related to these new products, including age transitions. We strongly encourage providers to review the guidance and visual aides in this document.

We will hold office hours to answer providers' questions about bivalent vaccines for young children:

- Wednesday, December 21, 8:30-9:30 a.m., register here
- Wednesday, January 4, 12:00-1:00 p.m., register here

If you are enrolled in the COVID-19 vaccination program, please order bivalent vaccine for your patient population in the <u>Citywide Immunization Registry</u>. Orders that were placed the week of December 6 began shipping on Monday, December 12. As a reminder, all COVID-19 vaccines will be shipped directly to facilities from the CDC vaccine distribution center (McKesson) or from Pfizer. Vaccine deliveries are no longer available from our local warehouse.

If you do not have COVID-19 vaccine at your facility, make sure to refer patients to a vaccination site. To find a vaccination site, visit <u>vaccinefinder.nyc.gov</u> or call 877-VAX-4NYC (877-829-4692). These resources will be updated soon to indicate locations offering bivalent boosters for young children.

Thank you for continuing to promote and protect the health of New Yorkers.

Sincerely,

Jane R. Zucker, MD, MSc

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Assistant Commissioner

Bureau of Immunization

New York City Department of Health and Mental Hygiene