

NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE Dave A. Chokshi, MD, MSc Commissioner

February 9, 2022

Dear Colleague,

The Vaccines and Related Biologic Products Advisory Committee to the U.S. Food and Drug Administration (FDA) is meeting on February 15, 2022 to review Pfizer's COVID-19 vaccine data for children ages 6 months to 4 years and to vote on whether to recommend Emergency Use Authorization for this vaccine. If this vaccine is authorized for use, the Advisory Committee on Immunization Practices (ACIP) will meet shortly thereafter, followed by recommendations from the Centers for Disease Control and Prevention (CDC). The vaccine could begin arriving in provider offices in New York City as early as the week of February 21.

New York City providers will be able to pre-order Pfizer vaccine for children 6 months through 4 years in the <u>Citywide Immunization Registry</u> starting February 10. Please place orders now to ensure you can receive vaccine the week of February 21. The Pfizer vaccine for children ages 6 months through 4 years must be ordered separately from other vaccine products. COVID-19 vaccine products for people ages 5 years and older cannot be used to vaccinate younger children. As a reminder, providers cannot administer COVID-19 vaccine to children 6 months through 4 years until the CDC issues a recommendation for vaccination of this age group.

Orders for Pfizer COVID-19 vaccine for children 6 months through 4 years will be in increments of 100 doses. There will 10 doses per vial. The CVX code for reporting to CIR is 219, and the NDC-11 code is 59267-0078-04. Orders will include diluent and other ancillary supplies configured specifically for this age group. The vaccine vial will have a distinctive maroon cap. As a reminder, providers will not be penalized for COVID-19 vaccine wastage. It is preferable to puncture a vial to vaccinate even one child, rather than miss an opportunity vaccinate.

Reconstitution will use a different volume of diluent than the formulation for other Pfizer COVID-19 vaccines; see table on the following page for details. As with the Pfizer gray and orange cap vaccines, the maroon cap vaccine can be stored in the refrigerator for up to 10 weeks and in an ultra-cold freezer (between -90°C to -60°C) for up to nine months. Regular freezers cannot be used to store any Pfizer COVID-19 vaccine products. The vaccine vials do not contain the vaccine expiration date. The date on the vial below the lot number is the manufacture date. The expiration date for the vaccine is 9 months after the manufacture date if the vaccine is stored in an ultra-cold unit.

Note that the vials for the maroon cap vaccine may have a label indicating the product is for children 2 years to <5 years *or* 6 months to 4 years; however, final age eligibility will be based on FDA authorization and CDC recommendations. **If authorized by FDA and recommended by**



CDC, maroon vials with labels stating for use in children 2 years to <5 years can be used for children 6 months to 4 years.

If you have any questions, please email <u>COVIDVax@health.nyc.gov</u>. For enrollment in the COVID-19 vaccination program go to <u>VPAS (vaccineagreement.org)</u>. Thank you for your commitment to promoting and protecting the health of New Yorkers.

Sincerely,

Jane R. Zucker, MD, MSc Assistant Commissioner Bureau of Immunization

Pfizer-BioNTech COVID-19 Vaccine Products

PRELIMINARY – SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION/APPROVAL; CDC DOCUMENT – SHARED FOR JURISDICTIONAL PLANNING PURPOSES ONLY

	Current Products		Future Product
Age Indications ^a	12 years and older	5 through 11 years	6 months through 4 years ^d
Vial Cap Color and Label with Color Border	GRAY		MAROON
Preparation	Do Not Dilute	Dilute Before Use	Dilute Before Use
Amount of Diluent Needed per $\mbox{Vial}^{\mbox{\tiny b}}$	Do Not Dilute	1.3 mL	2.2 mL
Dose Volume/Dose	0.3 mL/ 30 mcg	0.2 mL/ 10 mcg	0.2 mL/3 mcg
Doses per Vial	6 doses per vial	10 doses per vial (after dilution)	10 doses per vial (after dilution)
Storage Conditions			
ULT Freezer (-90°C to -60°C) ^c	9 months	9 months	9 months
Freezer (-25°C to -15°C)	DO NOT STORE	DO NOT STORE	DO NOT STORE
Refrigerator (2°C to 8°C)	10 weeks	10 weeks	10 weeks
Room Temperature (8°C to 25°C)	12 hours prior to first puncture (including any thaw time)	12 hours prior to first puncture (including any thaw time)	12 hours prior to first puncture (including any thaw time)
After First Puncture (2°C to 25°C)	Discard after 12 hours	Discard after 12 hours	Discard after 12 hours

* Use the appropriate product based on the age of the recipient. * Diluent: Sterile 0.9% Sodium Chloride Injection, USP. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent. * Regardless of storage condition, vaccines should not be used after 9 months from the date of manufacture printed on the vial and cartons.

^d The vaccine is currently under emergency use authorization review by the Food and Drug Administration (FDA) for children 6 months through 4 years old.