

September 6, 2022

Dear Colleague,

On September 1, 2022, the Centers for Disease Control and Prevention (CDC) recommended that everyone ages 12 years and older should receive one age-appropriate bivalent mRNA COVID-19 booster dose at least 2 months after completion of any FDA-approved or FDA-authorized monovalent COVID-19 primary series or last monovalent booster dose. The bivalent boosters contain two mRNA components of SARS-CoV-2 virus, one of the ancestral strain of SARS-CoV-2 and one of common portions of the BA.4 and BA.5 lineages of the Omicron variant. People cannot get a bivalent COVID-19 booster without first completing at least a monovalent primary series. Age-appropriate homologous and heterologous boosters are allowed; there is no preference for homologous or heterologous boosters. These recommendation follow Emergency Use Authorizations (EUAs) by the U.S. Food and Drug Administration (FDA). CDC's Clinical Considerations have also been updated.

The Health Department is holding office hours to answer questions about the new recommendations on Thursday, September 8 from 9-10am. Participants should register <a href="here">here</a>. Separately, the CDC will be hosting a webinar for providers focused on recommendations for bivalent COVID-19 booster doses to be held on Tuesday, September 13, 2022 from 2pm to 3pm (link <a href="here">here</a>).

Two bivalent COVID-19 booster formulations are now available:

- **Pfizer bivalent booster,** authorized for people ages 12 years and older: Gray cap, 30 mcg / 0.3 mL dose, no dilution, storage in an ultra-cold freezer until expiration or refrigerator (2°C-8°C) up to 10 weeks
- Moderna bivalent booster, authorized for people ages 18 years and older: Dark blue cap, gray label border, 50 mcg / 0.5 mL dose, no dilution, storage in a freezer (15°C to 50°C) until expiration or refrigerator (2°C to 8°C) up to 30 days

Given that the bivalent formulations have identical or similar cap colors as the monovalent formulations for each manufacturer, providers must pay careful attention to the vial labels to prevent vaccine administration errors. Additional information about vaccine labeling and formulations is attached.

All providers should stop administering Moderna and Pfizer monovalent COVID-19 vaccine boosters to people ages 12 years and older, effective immediately.

The recommendations for children under 12 years of age are unchanged. Children ages 5 through 11 years who received Pfizer primary series should receive 1 monovalent booster dose. At this time, children ages 6 to 11 years who received Moderna primary series and children under 5 years of age cannot receive any type of booster.

People who recently had COVID-19 infection may consider delaying any COVID-19 vaccination, including bivalent booster vaccination, by 3 months from symptom onset or positive test (if infection was asymptomatic). Studies have shown that increased time between infection and vaccination may result in an improved immune response to vaccination. Individual factors such as risk of COVID-19 severe disease, COVID-19 community level, or characteristics of the predominant SARS-CoV-2 strain should be taken into account when determining whether to delay getting a COVID-19 vaccination after infection.

The rationale for bivalent boosters is based on observed declines in neutralizing antibodies and <u>vaccine</u> <u>effectiveness</u> after monovalent primary series and booster doses, as well as <u>modeling projections</u> about the impact of potential future variants. Studies conducted by <u>Pfizer</u> and <u>Moderna</u> demonstrated that inclusion of a second SARS-CoV-2 variant in the vaccine broadens the antibody response, though these studies used bivalent boosters containing ancestral and BA.1 strains, whereas the available bivalent boosters contain ancestral and BA.4/BA.5 strains. Both the Pfizer and Moderna bivalent booster trials found that, compared with the monovalent booster, the bivalent booster resulted in higher antibody titers for Omicron variants and other SARS-CoV-2 variants, as well as titers that were as high or higher for ancestral SARS-CoV-2. Reactogenicity profiles were similar for recipients of bivalent and monovalent boosters; risk of myocarditis is unknown but expected to be similar to <u>monovalent boosters</u>.

**COVID-19 vaccines.** Getting multiple vaccines at the same visit increases the chance that a person will be up to date with their vaccinations. Generally, COVID-19 vaccines administered with seasonal influenza vaccine showed similar immunogenicity and similar or slightly higher reactogenicity; no safety concerns were identified.

The only exception to coadministration of COVID-19 vaccines is for JYNNEOS vaccine for monkeypox virus. In the current outbreak, JYNNEOS post-exposure prophylaxis should not be delayed because of recent receipt of a COVID-19 vaccine. However, people, particularly adolescent or young adult males, might consider waiting 4 weeks after JYNNEOS vaccination before receiving a COVID-19 vaccine due to the unknown risk of myocarditis and/or pericarditis with coadministration.

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

Sincerely,

Jane R. Zucker, MD, MSc Assistant Commissioner

Jane R. Zicher

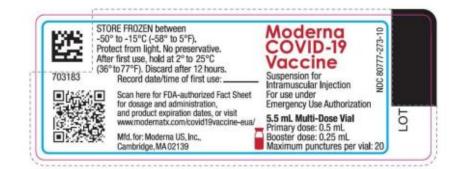
Bureau of Immunization

## Moderna COVID-19 Vaccine Formulations

	Monovalent Product	Monovalent Product	Bivalent Product
Authorized for ages	12 years and older	6–11 years	18 years and older
Vial cap color	Red	Dark blue	Dark blue
Label border color	Light blue	Purple	Gray
Dose (mRNA concentration)	100 mcg (primary dose)	50 mcg (primary dose)	50 mcg (booster dose) (25 mcg original, 25 mcg Omicron BA.4/BA.5)
Injection volume	0.5 mL	0.5 mL	0.5 mL
Dilution required	No	No	No
Beyond-use date	12 hours	12 hours	12 hours
Storage	Freezer (-15°C to -50°C) until expiration; Refrigerator (2°C to 8°C) up to 30 days	Freezer (-15°C to -50°C) until expiration; Refrigerator (2°C to 8°C) up to 30 days	Freezer (-15°C to -50°C) until expiration; Refrigerator (2°C to 8°C) up to 30 days

## Moderna Labels

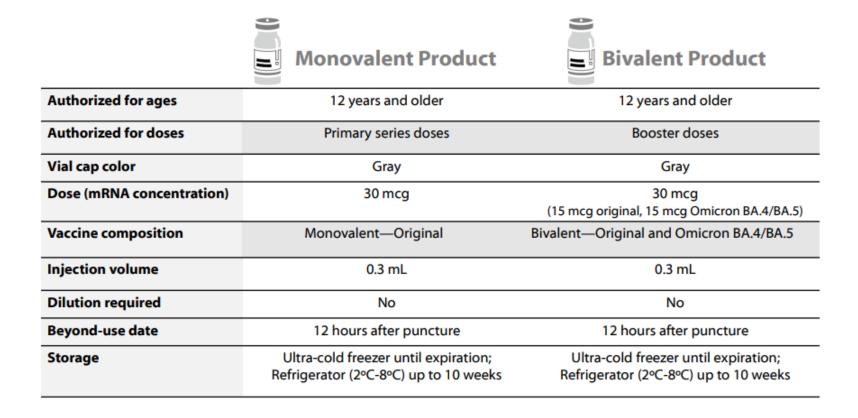
Monovalent label Primary series only Ages 12 years and older



Bivalent label Booster dose only Ages 18 years and older

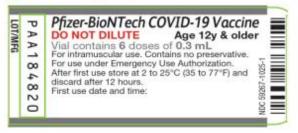


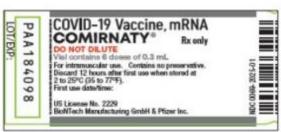
## Pfizer COVID-19 Vaccine Formulations



## Pfizer Labels

Monovalent label
Primary series only
Ages 12 years and older





Bivalent label Booster dose only Ages 12 years and older

