

September 2nd, 2022

COM-2022-045

Dear provider of healthcare-related services,

The Food and Drug Administration (FDA) amended the emergency use authorizations (EUAs) of the Moderna and Pfizer-BioNTech COVID-19 vaccines to authorize bivalent formulations of the vaccines for use as a single booster dose at least two months following primary or booster vaccination. These bivalent formulations include an mRNA component of the original strain to provide an immune response that is broadly protective against COVID-19 and an mRNA component with the omicron variant BA.4 ad BA.5 lineages to take aim at the Omicron subvariants that are dominant in the United States.

Pfizer-BioNTech: Eligibility and Description

PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT (ORIGINAL AND OMICRON BA.4/BA.5)

BOOSTER DOSE FOR 12 YEARS OF AGE AND OLDER DO NOT DILUTE

 Pfizer COVID-19 Vaccine, Bivalent is recommended in individuals 12 years of age and older. It is supplied in single-dose and multiple-dose vials with gray caps and labels with gray borders.

Moderna: Eligibility and Description

MODERNA COVID-19 VACCINE, BIVALENT (ORIGINAL AND OMICRON BA.4/BA.5)

BOOSTER DOSE FOR 18 YEARS OF AGE AND OLDER





 Moderna COVID-19 Vaccine, Bivalent is recommended in individuals 18 years of age and older. It is supplied in a multiple-dose vial with a dark blue cap and a label with a gray border.

The bivalent booster recommendation <u>replaces</u> previous booster recommendations for people ages 12 years and older. In summary, everyone ages 12 years and older is recommended to receive 1 age-appropriate bivalent mRNA booster dose after completion of any FDA-approved or FDA-authorized monovalent primary series or last monovalent booster dose. The Centers for Disease Control and Prevention (CDC) has endorsed the updated COVID-19 boosters.

Please refer to the following resources for more information:

- 1. FDA News Release: COVID-19 Update: FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose
- 2. Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) Fact Sheet for Healthcare Providers
- 3. <u>Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) Fact</u> Sheet for Healthcare Providers
- 4. CDC Stay Up to Date with COVID-19 Vaccines Including Boosters

The situation with the COVID-19 pandemic is dynamic and constantly changing. We strongly encourage the frequent revision of updated information provided by the FDA, CDC, and the World Health Organization (WHO), to assure that your practices are consistent with the most updated information.

PharmPix is committed to the health and wellness of our members, and to support you as the COVID-19 pandemic continues to evolve. If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 220.

Kind regards,

Clinical Department

