Indian Health Service
National Pharmacy and Therapeutics Committee
COVID-19 Emerging Treatments Update

October 12, 2022

FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose in Younger Age Groups

On October 12, 2022, the U.S. Food and Drug Administration amended the emergency use authorizations (EUAs) of the Moderna COVID-19 Vaccine, Bivalent and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent to authorize their use as a single booster dose in younger age groups. The Moderna COVID-19 Vaccine, Bivalent is authorized for administration at least two months following completion of primary or booster vaccination in children down to six years of age. The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is authorized for administration at least two months following completion of primary or booster vaccination in children down to five years of age.

On October 12, 2022, the U.S. Centers for Disease Control and Prevention (CDC) Director, Rochelle Walensky, MD, also endorsed the FDA's decision by signing a memorandum to expand the use of updated (bivalent) COVID-19 vaccines to children and adolescents ages 5 through 11 years.

Eligibility and timing of single booster doses:

- Individuals 6 years of age and older are eligible for a single booster dose of the **Moderna COVID-19 Vaccine, Bivalent** 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.
- Individuals 5 years of age and older are eligible for a single booster dose of the **Pfizer-BioNTech COVID-19 Vaccine, Bivalent** if it has been at least 2 months since they have completed primary vaccination or have received the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

COVID-19 Bivalent Vaccine Booster Notes:

- The authorized bivalent COVID-19 vaccines, or updated boosters, include an mRNA component of the original strain to provide an immune response that is broadly protective against COVID-19 and an mRNA component in common between the omicron variant BA.4 and BA.5 lineages to provide better protection against COVID-19 caused by the omicron variant.
- The BA.4 and BA.5 lineages of the omicron variant are currently causing most cases of COVID-19 in the U.S. and are predicted to circulate this fall and winter. In June, the agency's Vaccines and Related Biological Products Advisory Committee voted overwhelmingly to include an omicron component in COVID-19 booster vaccines.
- For each bivalent COVID-19 vaccine, the FDA based its decision on the totality of available evidence, including extensive safety and effectiveness data for each of the monovalent mRNA COVID-19 vaccines, safety and immunogenicity data obtained from a clinical study of a bivalent COVID-19 vaccine that contained mRNA from omicron variant BA.1 lineage that is similar to each of the vaccines being authorized, and nonclinical data obtained using a bivalent COVID-19 vaccine that contained mRNA of the original strain and mRNA in common between the BA.4 and BA.5 lineages of the omicron variant.
- Based on the data supporting each of these authorizations, the bivalent COVID-19 vaccines are expected to provide increased protection against the currently circulating omicron variant. Individuals who receive a bivalent COVID-19 vaccine may experience side effects commonly reported by individuals who receive authorized or approved monovalent mRNA COVID-19 vaccines.
- With this authorization, the FDA has also revised the EUA of the Moderna COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine to remove the use of the monovalent Moderna and Pfizer-BioNTech COVID-19 vaccines for booster administration for individuals ≥6 years of age and ≥5 years of age, respectively. These monovalent vaccines continue to be authorized for use for administration of a primary series for individuals 6 months of age and older as described in the letters of authorization.

Data Supporting the Moderna COVID-19 Vaccine, Bivalent Authorization

- The data supporting FDA's authorization of a single booster dose of the Moderna COVID-19 Vaccine, Bivalent for both the 6 years through 11 years age group and 12 through 17 years age group is based on the FDA's previous analysis of immune response and safety data from a clinical study in adults 18 years of age and older who received a booster dose of Moderna's investigational bivalent COVID-19 vaccine that contained a component of the original strain of SARS-CoV-2 and a component of Omicron lineage BA.1.

- Safety and effectiveness data supporting the Moderna COVID-19 Vaccine, Bivalent authorization as a booster dose in individuals 18 years of age and older can be found here.

Data Supporting the Pfizer-BioNTech COVID-19 Vaccine, Bivalent Authorization

- The data supporting the authorization of a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent for individuals 5 through 11 years of age is based in part on the FDA's previous analysis of immune response and safety data from a clinical study in adults greater than 55 years of age who received a booster dose of a Pfizer-BioNTech's investigational bivalent COVID-19 vaccine that contained a component of the original strain of SARS-CoV-2 and a component of Omicron lineage BA.1. In addition, the authorization is based on the FDA's previous analysis of safety and effectiveness data of a booster dose of monovalent Pfizer-BioNTech COVID-19 Vaccine in children 5 through 11 years of age.
- Safety and effectiveness data supporting the Pfizer-BioNTech COVID-19 Vaccine, Bivalent authorization as a booster dose in individuals 12 years of age and older can be found here.

FACT SHEETS: COVID-19 Vaccine, Bivalent

1.	Moderna:	Healthcare Providers (≥6 years)	-or-	Recipients and Caregivers (≥6 years)
2.	Pfizer-BioNTech:	Healthcare Providers (5-11 years)	-or-	Recipients and Caregivers (5-11 years)
		Healthcare Providers (≥12 years)	-or-	Recipients and Caregivers (≥12 years)

Mandatory Requirements under the Emergency Use Authorization *(all requirements must be met)*

- Use each COVID-19 Vaccine, Bivalent only in authorized patients described in the respective Fact Sheets.
- Communicate to recipients or caregivers, as age appropriate, information consistent with the "Fact Sheet for Recipients and Caregivers" prior to the individual receiving each respective COVID-19 Vaccine, Bivalent.
- Include vaccination information in the local jurisdiction's Immunization Information System or other system.
- Mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
  - Vaccine administration errors whether or not associated with an adverse event,
  - Serious adverse events (irrespective of attribution to vaccination),
  - Cases of myocarditis and pericarditis
  - Cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and
  - Cases of COVID-19 that result in hospitalization or death.
- *Federal, Tribal, and Urban programs are all encouraged to* ***put "IHS" into field #26 of the form.***

References:
1. U.S. Food and Drug Administration. Coronavirus (COVID-19) Update: FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose in Younger Ages. Published October 12, 2022.
2. U.S. Centers for Disease Control and Prevention. Media Statement. CDC Expands Updated COVID-19 Vaccines to Include Children Ages 5 Through 11. Published October 12, 2022.