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

April 18, 2023

FDA Authorizes Changes to Simplify Use of Bivalent mRNA COVID-19 Vaccines

On April 18, 2023, the U.S. Food and Drug Administration (FDA) amended the Emergency Use Authorizations (EUAs) of the Moderna and Pfizer-BioNTech COVID-19 bivalent mRNA vaccines to simplify the vaccination schedule for most individuals. **This action included authorizing the current bivalent vaccines (original plus Omicron BA.4/BA.5 strains) to be used for all doses administered to individuals 6 months of age and older, including for an additional dose or doses for certain populations.** *The monovalent Moderna and Pfizer-BioNTech COVID-19 vaccines are no longer authorized for use in the United States.*

Parents and caregivers should be aware of the following information:

- Most individuals, depending on age, previously vaccinated with a monovalent COVID-19 vaccine who have not yet received a dose of a bivalent vaccine may receive a single dose of a bivalent vaccine.
- Most individuals who have already received a single dose of the bivalent vaccine are not currently eligible for another dose. The FDA intends to make decisions about future vaccination after receiving recommendations on the fall strain composition at an FDA advisory committee meeting in June.
- **Individuals 65 years of age and older who have received a single dose of a bivalent vaccine may receive one additional dose at least four months following their initial bivalent dose.**
- Most individuals with certain kinds of immunocompromise who have received a bivalent COVID-19 vaccine may receive a single additional dose of a bivalent COVID-19 vaccine at least 2 months following a dose of a bivalent COVID-19 vaccine, and additional doses may be administered at the discretion of, and at intervals determined by, their healthcare provider. However, for immunocompromised individuals 6 months through 4 years of age, eligibility for additional doses will depend on the vaccine previously received.
- Most unvaccinated individuals may receive a single dose of a bivalent vaccine, rather than multiple doses of the original monovalent mRNA vaccines.
- Children 6 months through 5 years of age who are unvaccinated may receive a two-dose series of the Moderna bivalent vaccine (6 months through 5 years of age) OR a three-dose series of the Pfizer-BioNTech bivalent vaccine (6 months through 4 years of age). Children who are 5 years of age may receive two doses of the Moderna bivalent vaccine or a single dose of the Pfizer-BioNTech bivalent vaccine.
- Children 6 months through 5 years of age who have received one, two or three doses of a monovalent COVID-19 vaccine may receive a bivalent vaccine, but the number of doses that they receive will depend on the vaccine and their vaccination history.

Available data show that almost all of the U.S. population 5 years of age and older now have antibodies as a result of either vaccination or infection against SARS-CoV-2. The use of bivalent COVID-19 vaccines for all doses administered to individuals 6 months of age and older is supported by the data described below, as well as post-marketing data, including real-world data, with the monovalent and bivalent mRNA COVID-19 vaccines, which have been administered to millions of people, including young children. A second bivalent dose for individuals 65 years of age and older is supported by data showing the waning of immunity in this population over time and its restoration by an additional dose. Additionally, based on evidence from studies conducted previously, immunocompromised individuals may require additional doses.

Moderna COVID-19 Vaccine, Bivalent

The safety and effectiveness of Moderna COVID-19 Vaccine, Bivalent is based on FDA's previous analyses of clinical trials data of monovalent Moderna COVID-19 Vaccine in individuals 6 months of age and older and an

investigational bivalent Moderna COVID-19 vaccine (original and omicron BA.1) in individuals 18 years of age and older.

In addition, effectiveness of a single dose is supported by the FDA's analysis of immune response data from clinical studies in which 145 individuals 6 years of age and older who had evidence of prior SARS-CoV-2 infection and 1,376 individuals 6 years of age and older without evidence of prior SARS-CoV-2 infection had received two doses of monovalent Moderna COVID-19 Vaccine. The immune response after one dose of vaccine among participants with evidence of prior infection was comparable to the immune response after two doses among participants without evidence of prior infection.

The data accrued with the investigational bivalent Moderna COVID-19 vaccine (original and omicron BA.1) and with the monovalent Moderna COVID-19 Vaccine are relevant to the Moderna COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process.

Pfizer-BioNTech COVID-19 Vaccine, Bivalent

The safety and effectiveness of Pfizer-BioNTech COVID-19 Vaccine, Bivalent is based on the FDA's previous analyses of clinical trials data of monovalent Pfizer-BioNTech COVID-19 Vaccine for use in individuals 6 months of age and older, an investigational bivalent Pfizer-BioNTech COVID-19 vaccine (original and omicron BA.1) in individuals greater than 55 years of age, as well as safety data with Pfizer-BioNTech COVID-19 Vaccine, Bivalent (original and omicron BA.4/BA.5) in individuals 6 months of age and older and immune response data in individuals 6 months through 4 years of age.

In addition, effectiveness of a single dose is supported by observational data from England on the effectiveness of one dose of monovalent Pfizer-BioNTech COVID-19 Vaccine. Among individuals 12 to 17 years of age who had received only one dose of Pfizer-BioNTech COVID-19 Vaccine, those who had evidence of previous infection with alpha, delta or omicron variants had increased protection against symptomatic omicron infection compared with those with no evidence of previous infection.

The data accrued with the investigational Pfizer-BioNTech bivalent COVID-19 vaccine (original and omicron BA.1) and with the monovalent Pfizer-BioNTech COVID-19 Vaccine are relevant to the Pfizer-BioNTech COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process.

With these authorizations, the fact sheets have been updated and consolidated for the Moderna COVID-19 Vaccine, Bivalent and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. Each vaccine now has one fact sheet for healthcare providers and one fact sheet for recipients and caregivers, rather than different fact sheets for the various authorized age groups.

Vaccines and Related Biological Products Advisory Committee

These authorizations follow discussions that occurred during a meeting with the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) on Jan. 26, 2023. At that time, by a unanimous vote, the committee recommended harmonizing the strain composition of COVID-19 vaccines used in the U.S. There was also support for simplifying the vaccine dosing schedule.

In June, the FDA will hold a meeting of its VRBPAC to discuss the strain composition of the COVID-19 vaccines for fall of 2023. Much like the FDA does yearly with the influenza vaccines, the FDA will seek input from the committee on which SARS-CoV-2 variants and lineages are most likely to circulate in the upcoming year. Once the specific strains are selected for the COVID-19 vaccines, the FDA expects manufacturers to make updated formulations of the vaccines for availability this fall.

Reference(s):

1. U.S. Food & Drug Administration. Coronavirus (COVID-19) Update: FDA Authorizes Changes to Simplify Use of Bivalent mRNA COVID-19 Vaccines. Published online April 18, 2023.