



December 9, 2022

FDA Authorizes Updated (Bivalent) COVID-19 Vaccines for Children Down to 6 Months of Age

On December 8, 2022, the U.S. Food and Drug Administration (FDA) amended the emergency use authorizations (EUAs) of the updated (bivalent) Moderna and Pfizer-BioNTech COVID-19 vaccines to include use in children down to 6 months of age. Following FDA action, the CDC expanded the use of updated (bivalent) COVID-19 vaccines for children ages 6 months through 5 years on December 9, 2022.

Parents and caregivers should be aware of the following information:

- Children 6 months through 5 years of age who received the original (monovalent) Moderna COVID-19 Vaccine are now eligible to receive a single booster of the updated (bivalent) Moderna COVID-19 Vaccine two months after completing a primary series with the monovalent Moderna COVID-19 Vaccine.
- Children 6 months through 4 years of age who have not yet begun their three-dose primary series of the Pfizer-BioNTech COVID-19 Vaccine or have not yet received the third dose of their primary series will now receive the updated (bivalent) Pfizer-BioNTech COVID-19 vaccine as the third dose in their primary series following two doses of the original (monovalent) Pfizer-BioNTech COVID-19 Vaccine.
- Children 6 months through 4 years of age who have already completed their three-dose primary series with the original (monovalent) Pfizer-BioNTech COVID-19 Vaccine will not be eligible for a booster dose of an updated bivalent vaccine at this time. Children in this age group who already completed their primary series would still be expected to have protection against the most serious outcomes from the currently circulating omicron variant. The data to support giving an updated bivalent booster dose for these children are expected in January. The agency is committed to evaluating those data as quickly as possible.
- The Moderna and Pfizer-BioNTech bivalent COVID-19 vaccines include an mRNA component corresponding to the original strain to provide an immune response that is broadly protective against COVID-19 and an mRNA component corresponding to the omicron variant BA.4 and BA.5 lineages to provide better protection against COVID-19 caused by the omicron variant.
- Individuals who receive the updated (bivalent) vaccines may experience similar side effects reported by individuals who received previous doses of the original (monovalent) mRNA COVID-19 vaccines.
- The fact sheets for both bivalent COVID-19 vaccines for recipients and caregivers and for healthcare providers include information about the potential side effects, as well as the risks of myocarditis and pericarditis.

Moderna COVID-19 Vaccine, Bivalent

The monovalent Moderna COVID-19 Vaccine is authorized as a two-dose primary series in individuals six months of age and older and as a third primary series dose for individuals 6 months of age and older who have been determined to have certain kinds of immunocompromise. With the authorization, the Moderna COVID-19 Vaccine, Bivalent is now authorized for administration in those 6 months through 5 years of age as a single booster dose at least 2 months after completion of primary vaccination with the monovalent Moderna COVID-19 Vaccine. The Moderna COVID-19 Vaccine, Bivalent is also authorized for use in individuals 6 years and older as a single booster dose at least two months after completion of either primary vaccination with any authorized or approved COVID-19 vaccine, or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

For authorization of a single booster dose of the Moderna COVID-19 Vaccine, Bivalent for children 6 months through 5 years of age, the FDA relied on immune response data that it had previously evaluated from a clinical study in adults of a booster dose of Moderna's investigational bivalent COVID-19 vaccine that contained a component corresponding to the original strain of SARS-CoV-2 and a component corresponding to the omicron lineage BA.1.

In addition, the FDA conducted an analysis of data from a clinical study that compared the immune response among 56 study participants 17 months through 5 years of age who received a single booster dose of monovalent Moderna COVID-19 Vaccine at least six months after completion of a two-dose primary series of the vaccine to the immune response among approximately 300 study participants aged 18 to 25 years who received a two-dose primary series of monovalent Moderna COVID-19 Vaccine in a previous study which determined the vaccine to be effective in preventing COVID-19. The immune response to the booster dose of monovalent Moderna COVID-19 Vaccine in the 17 months through 5 years' age group was comparable to the immune response to the two-dose primary series in the adult participants.

The safety of a single booster dose of the Moderna COVID-19 Vaccine, Bivalent for children 6 months through 5 years of age is supported by safety data from a clinical study which evaluated a booster dose of Moderna's investigational bivalent COVID-19 vaccine (original and omicron BA.1), safety data from clinical trials which evaluated primary and booster vaccination with the monovalent Moderna COVID-19 Vaccine, and postmarketing safety data with the monovalent Moderna COVID-19 Vaccine and Moderna COVID-19 Vaccine, Bivalent.

In one clinical study, the safety of a single booster dose of monovalent Moderna COVID-19 Vaccine was evaluated in 145 clinical study participants 6 months through 5 years of age who received a booster dose of monovalent Moderna COVID-19 Vaccine at least six months after completion of the monovalent Moderna COVID-19 Vaccine two-dose primary series. The most commonly reported side effects after a booster dose of the monovalent Moderna COVID-19 Vaccine across this age group included pain, redness and swelling at the injection site, swelling/tenderness of the lymph nodes of the injected arm or thigh, and fever. In clinical study participants 17 months through 36 months of age, other commonly reported side effects included irritability/crying, sleepiness, and loss of appetite. In clinical trial participants 37 months through 5 years of age, other commonly reported side effects included fatigue, headache, muscle pain, joint pain, chills, and nausea/vomiting.

The data accrued with the investigational Moderna bivalent 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

With this authorization, children 6 months through 4 years of age who have not yet received the third dose of the three-dose primary series with the monovalent Pfizer-BioNTech COVID-19 Vaccine will now receive the Pfizer-BioNTech COVID-19 Vaccine, Bivalent as the third dose of the primary series. The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is also authorized for administration in individuals 5 years of age and older as a single booster dose at least two months after completion of either primary vaccination with any authorized or approved COVID-19 vaccine, or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

With this action, the monovalent Pfizer-BioNTech COVID-19 Vaccine is no longer authorized for use as the third dose of the three-dose primary series in children 6 months through 4 years of age. The monovalent Pfizer-BioNTech COVID-19 Vaccine remains authorized for administration as the first two doses of the three-dose primary series in individuals 6 months through 4 years of age, as a two-dose primary series for individuals 5 years of age and older, and as a third primary series dose for individuals 5 years of age and older who have been determined to have certain kinds of immunocompromise.

The authorization of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent for administration as the third dose of a three-dose primary series following two doses of the monovalent Pfizer-BioNTech COVID-19 Vaccine in children 6 months through 4 years of age is supported by the FDA's previous analyses of the effectiveness of primary vaccination with the monovalent Pfizer-BioNTech COVID-19 Vaccine in individuals 16 years of age and older and individuals 6 months through 4 years of age, and previous analyses of immune response data in adults greater than 55 years of age who had received a two-dose primary series and one booster dose with the monovalent Pfizer-BioNTech COVID-19 Vaccine and a second booster dose with the investigational Pfizer-BioNTech bivalent COVID-19 vaccine (original and omicron BA.1).

The safety of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent for administration as the third dose of a three-dose primary series following two doses of the monovalent Pfizer-BioNTech COVID-19 Vaccine in children 6 months through 4 years of age is based on safety data from a clinical study which evaluated a booster dose of Pfizer-BioNTech's investigational bivalent COVID-19 vaccine (original and omicron BA.1) in individuals greater than 55 years of age, safety data from clinical trials which evaluated primary vaccination in individuals 6 months of age and older with the monovalent Pfizer-BioNTech COVID-19 Vaccine, safety data from clinical trials which evaluated booster vaccination in individuals 5 years of age and older with the monovalent Pfizer-BioNTech COVID-19 Vaccine and post-marketing safety data with the monovalent Pfizer-BioNTech COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

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.

Reference(s):

1. U.S. Food & Drug Administration. [FDA Authorizes Updated \(Bivalent\) COVID-19 Vaccines for Children Down to 6 Months of Age](#). Published online December 8, 2022.
2. U.S. Centers for Disease Control and Prevention. [CDC Expands Updated COVID-19 Vaccines to Include Children Ages 6 Months through 5 Years](#). Published online December 9, 2022.