



June 20, 2022

## FDA Authorizes Moderna and Pfizer-BioNTech COVID-19 Vaccines for Children Down to 6 Months of Age

On June 17, 2022, the U.S. Food and Drug Administration (FDA) authorized emergency use of the Moderna COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 to include use in children down to 6 months of age.

- For the [Moderna COVID-19 Vaccine](#), the FDA amended the emergency use authorization (EUA) to include use of the vaccine in individuals 6 months through 17 years of age. The vaccine had been authorized for use in adults 18 years of age and older.
- The Moderna COVID-19 Vaccine is administered as a primary series of two doses, one month apart, to individuals 6 months through 17 years of age. The vaccine is also authorized to provide a third primary series dose at least one month following the second dose for individuals in this age group who have been determined to have certain kinds of immunocompromise.
- For the [Pfizer-BioNTech COVID-19 Vaccine](#), the FDA amended the EUA to include use of the vaccine in individuals 6 months through 4 years of age. The vaccine had been authorized for use in individuals 5 years of age and older.
- The Pfizer-BioNTech COVID-19 Vaccine is administered as a primary series of three doses in which the initial two doses are administered three weeks apart followed by a third dose administered at least 8 weeks after the 2nd dose in individuals 6 months through 4 years of age.

\*\* While the FDA [Emergency Use Authorization](#) for Moderna's COVID-19 vaccine includes children and adolescents up to age 17 years, the **CDC Advisory Committee on Immunization Practices plans to review safety and efficacy data for the 6-17 year old age group on June 23, 2022 before issuing a recommendation**. Implementation of Moderna's COVID vaccine for children aged 6-17yo is on hold pending ACIP review and CDC action, expected later this week. Additional information will be forthcoming.

### Vaccination Provider Educational Resource Compendium

- Moderna FACT SHEETS: (6 months to 5 years) → [Health Care Provider](#) --OR-- [Recipients/Caregivers](#)
- Moderna COVID-19 [Vaccine Wall Chart](#)
- Pfizer FACT SHEETS: (6 months to 4 years) → [Health Care Provider](#) --OR-- [Recipients/Caregivers](#)
- Pfizer [Dear Healthcare Provider Letter](#)
- Pfizer-BioNTech COVID-19 [Vaccine Wall Chart](#)
- At-A-Glance [COVID-19 Vaccination Schedules](#)
- CDC Pediatric COVID-19 Vaccination [Operational Planning Guide](#)
- [CDC Resources](#) to Promote the COVID-19 Vaccine for Children & Teens

### Moderna COVID-19 Vaccine for Individuals 6 Months through 5 Years of Age

The effectiveness and safety data evaluated and analyzed by the FDA for the Moderna COVID-19 Vaccine to support the EUA for these pediatric populations were generated in two ongoing, randomized, blinded, placebo-controlled clinical trials in the United States and Canada which enrolled infants, children and adolescents.

- **Children 6 months through 5 years of age:** Immune responses of a subset of 230 children 6 through 23 months and a subset of 260 children 2 through 5 years of age who received a two-dose primary series of the Moderna COVID-19 Vaccine at 25 micrograms (mcg) of messenger RNA (mRNA) per dose were compared to immune responses among 290 adults 18 through 25 years who received two higher doses of the vaccine in a previous study which determined the vaccine to be effective in preventing COVID-19. In these FDA analyses, the immune response to the vaccine, of both age groups of children, was comparable to the immune response of the adults.

An analysis of cases of COVID-19 occurring at least 14 days after the second dose among approximately 5,400 children in this age group without evidence of prior infection with SARS-CoV-2 was conducted during the time period in which the omicron variant was the predominant circulating strain. In this analysis, among participants 6 through 23 months of age, 64% of whom had blinded follow-up for more than two months after the second dose, the vaccine was 50.6% effective in preventing COVID-19. Among participants 2 through 5 years of age, 72% of whom had blinded follow-up for more than two months after the second dose, the vaccine was 36.8% effective in preventing COVID-19.

#### **=Safety Data=**

- **Children 6 months through 5 years of age:** Safety was evaluated in approximately 1,700 children 6 through 23 months of age who received the vaccine and 600 who received the placebo. Of these, approximately 1,100 vaccine recipients were followed for safety for at least two months following the second dose. For participants 2 through 5 years of age, approximately 3,000 received the vaccine and approximately 1,000 received a placebo; approximately 2,200 vaccine recipients were followed for safety for at least two months following the second dose. In clinical trial participants 6 months through 5 years of age, the most commonly reported side effects across all age subgroups included pain, redness and swelling at the injection site, fever and underarm (or groin) swelling/tenderness of lymph nodes in the same arm (or thigh) as the injection. In clinical trial participants 6 through 36 months of age, the most commonly reported side effects also included irritability/crying, sleepiness, and loss of appetite. In clinical trial participants 37 months through 5 years of age, the most commonly reported side effects also included fatigue, headache, muscle ache, chills, nausea/vomiting and joint stiffness.

#### **Pfizer-BioNTech COVID-19 Vaccine for Children 6 Months through 4 Years of Age**

The effectiveness and safety data evaluated and analyzed by the FDA for the Pfizer-BioNTech COVID-19 Vaccine were generated in an ongoing, randomized, blinded, placebo-controlled clinical trial in the United States and internationally, which enrolled infants and children.

- The effectiveness data to support the EUA in children 6 months through 4 years of age is based on a comparison of immune responses following three doses of the Pfizer-BioNTech COVID-19 Vaccine in a subset of children in this age group to the immune responses among adults 16 through 25 years of age who received two higher doses of the Pfizer-BioNTech COVID-19 Vaccine in a previous study which determined the vaccine to be effective in preventing COVID-19. The study was conducted in two age subgroups. The immune response to the vaccine of approximately 80 children, 6 through 23 months of age, and approximately 140 children, 2 through 4 years of age, were compared to the immune response of approximately 170 of the older participants. In these FDA analyses, the immune response to the vaccine for both age groups of children was comparable to the immune response of the older participants. An additional analysis pertaining to the occurrence of COVID-19 cases was determined not to be reliable due to the low number of COVID-19 cases that occurred in study participants.

#### **=Safety Data=**

- The available safety data to support the EUA in children 6 through 23 months of age include approximately 1,170 who received the vaccine and approximately 600 who received placebo; approximately 400 vaccine recipients were followed for safety for at least two months following the third dose. For the participants 2 through 4 years of age, approximately 1,800 received the vaccine and approximately 900 received placebo; approximately 600 vaccine recipients were followed for safety for at least two months following the third dose. The most commonly reported side effects in clinical trial participants 6 through 23 months of age who received the vaccine were irritability, decreased appetite, fever and pain, tenderness, redness and swelling at the injection site. These side effects were also reported for the vaccine recipients 2 through 4 years' age, in addition to fever, headache, and chills.

## Risks of Myocarditis and Pericarditis

The FDA and CDC safety surveillance systems have previously identified increased risks of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of tissue surrounding the heart) following vaccination with the Moderna COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine, particularly following the second dose. The observed risk is highest in males 18 through 24 years of age for the Moderna COVID-19 Vaccine and in males 12 through 17 years of age for the Pfizer-BioNTech COVID-19 Vaccine.

The FDA and the CDC analyses of available safety surveillance data from the U.S. and other countries on myocarditis outcomes continue to strengthen the evidence that most cases of myocarditis associated with the Moderna and Pfizer-BioNTech COVID-19 vaccines are characterized by rapid resolution of symptoms following conservative management, with no impact on quality of life reported by most patients who were contacted for follow-up at 90 days or more after reporting myocarditis.

## CDC ACIP Interim Clinical Considerations ([updated June 19, 2022](#))

- COVID-19 vaccines currently approved or authorized by FDA are effective in preventing serious outcomes of coronavirus disease 2019 (COVID-19), including severe disease, hospitalization, and death.
- Everyone ages 6 months and older in the United States should receive a COVID-19 primary series vaccination for the prevention of COVID-19.
- Everyone ages 5 years and older should receive at least 1 booster dose of COVID-19 vaccine if eligible (i.e., if a booster dose is FDA-approved or FDA-authorized for use in a specified population). Recommendations for booster dose(s) vary by age, COVID-19 vaccine product and immunocompetence.
- Janssen COVID-19 Vaccine should only be used in limited situations; Pfizer-BioNTech or Moderna COVID-19 Vaccines are preferred for primary and booster vaccination.
- Efforts to increase the number of people in the United States who are [up to date](#) with their COVID-19 vaccines remain critical to preventing illness, hospitalizations, and deaths from COVID-19.

### References:

1. U.S. Food and Drug Administration. [Coronavirus \(COVID-19\) Update: FDA Authorizes Moderna and Pfizer-BioNTech COVID-19 Vaccines for Children Down to 6 Months of Age](#). Published June 17, 2022.
2. U.S. Centers for Disease Control and Prevention. [Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States](#). Last updated: June 19, 2022.