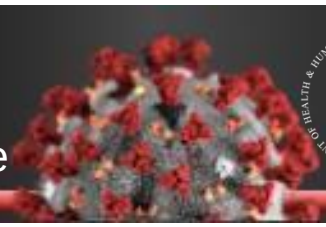
Indian Health Service
National Pharmacy and Therapeutics Committee
COVID-19 Emerging Treatments Update



June 24, 2022

CDC Recommends Moderna COVID-19 Vaccine for Children Ages 6 years through 17 years

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. **On June 23, 2022, the U.S. Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) reviewed the safety and efficacy data for the Moderna COVID-19 Vaccine in the 6 to 17-year-old age group and recommended use in this pediatric population.** Following CDC approval today, both the Moderna COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine are uniformly recommended and available for 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.

**** Vaccination Provider Educational Resource Compendium ****

Moderna FACT SHEETS: (6 months to 5 years) → HealthCare Provider *--OR--* Recipients/Caregivers
Moderna FACT SHEETS: (**6 years through 11 years**) → HealthCare Provider *--OR--* Recipients/Caregivers
Moderna FACT SHEETS: (**12 years and Older**) → HealthCare Provider *--OR--* Recipients/Caregivers
Moderna COVID-19 Vaccine: IMPORTANT PRESCRIBING INFORMATION (Ages 6 Years Through 11 Years)
Moderna 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 through 17 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 years through 11 years of age:** Immune responses of a subset of 320 children in this age group who received a two-dose primary series of the Moderna COVID-19 Vaccine at 50 mcg of mRNA per dose were compared to immune responses among 295 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 the FDA analysis, the immune response of the children to the vaccine was comparable to the immune response of the adults. An additional analysis pertaining to the occurrence of COVID-19 cases was determined not to be reliable due to low numbers of COVID-19 cases that occurred in participants.
- **Adolescents 12 through 17 years of age:** Immune responses of a subset of 340 adolescents in this age group who received a two-dose primary series of the Moderna COVID-19 Vaccine at 100 mcg of mRNA per dose were compared to immune responses among 296 adults 18 through 25 years who received two equivalent doses of the vaccine in a previous study which determined the vaccine to be effective in preventing COVID-19. In this analysis, the immune response of adolescents was comparable to the immune response of the older participants.

An analysis was also conducted of cases of COVID-19 occurring at least 14 days after the second dose among approximately 3,000 adolescents in this age group without evidence of prior infection with SARS-CoV-2, in which ~42% of participants had two or more months of blinded follow-up after the second dose. In this analysis, among participants 12 through 17 years of age, the vaccine was 93.3% effective in preventing COVID-19. The data for this analysis were obtained before the omicron variant became the predominant circulating strain.

=Safety Data=

The safety data to support the Moderna COVID-19 Vaccine EUA in individuals 6 through 17 years of age are as follows:

- **Children 6 through 11 years of age:** Safety was evaluated in approximately 3,000 children who received the vaccine and approximately 1,000 children who received placebo. The majority of vaccine recipients (98.7%) had at least two months of safety follow-up after their second dose.
- **Adolescents 12 through 17 years of age:** Safety was evaluated in approximately 2,500 participants who received the vaccine and 1,200 who received placebo. The majority of vaccine recipients (95.6%) had at least six months of follow-up after the second dose.

The most commonly reported side effects in the clinical trial participants for both the 6 through 11 age group and the 12 through 17 age group who received the vaccine include, pain, redness and swelling at the injection site, tiredness, headache, muscle pain, chills, joint pain, underarm swollen lymph nodes in the same arm as the injection, nausea and vomiting and fever.

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 Interim Clinical Considerations (*updated June 19, 2022*)

- COVID-19 vaccines currently FDA approved or authorized 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.

Vaccine providers should routinely monitor the CDC Interim Clinical Considerations for interval updates to the vaccine recommendations & schedule.

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.