FDA Authorizes Moderna and Pfizer-BioNTech COVID-19 Vaccines for Children Down to 6 Months of Age. Healthcare Providers cannot begin vaccination of these age groups until after FDA EUA approval and ACIP recommendations are signed by the CDC Director.

IMPORTANT/NEW COVID-19 Vaccine Information

- FDA Authorizes Moderna and Pfizer-BioNTech COVID-19 Vaccines for Children Down to 6 Months of Age
- Key Summary and Actions Items

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

The U.S. Food and Drug Administration 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.
- 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 ACIP is meeting to provide clinical considerations and the CDC director must sign the ACIP’s recommendations before Iowa healthcare providers may administer COVID-19 vaccine to these age groups. The ACIP is meeting June 17-18, 2022. Updated guidance is anticipated to be released Monday, June 20, 2022.

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.

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 eight weeks after the second dose in individuals 6 months through 4 years of age.
Key points:

- The FDA’s evaluation and analysis of the safety, effectiveness and manufacturing data of these vaccines was rigorous and comprehensive, supporting the EUAs.
- The agency determined that the known and potential benefits of the Moderna and Pfizer-BioNTech COVID-19 vaccines outweigh the known and potential risks in the pediatric populations authorized for use for each vaccine.
- Prior to making the decision to authorize these vaccines for the respective pediatric populations, the FDA’s independent Vaccines and Related Biological Products Advisory Committee was consulted and voted in support of the authorizations.

Resources:

- **Moderna COVID-19 Vaccine**
  - [Moderna Letter of Authorization](#)
  - [Moderna COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)](#) - 6 months through 5 years of age
  - [Moderna EUA Fact Sheet for Recipients and Caregivers](#) - 6 months through 5 years of age
  - [Moderna EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)](#) - 6 years through 11 years of age
  - [Moderna EUA Fact Sheet for Recipients and Caregivers](#) - 6 years through 11 years of age
  - [Moderna EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)](#) - 12 years and older and booster doses for 18 years of age and older
  - [Moderna EUA Fact Sheet for Recipients and Caregivers](#) - 12 years and older
  - [Moderna COVID-19 Vaccine](#)

- **Pfizer COVID-19 Vaccine**
  - [Pfizer Letter of Authorization](#)
  - [Pfizer COVID-19 EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)](#) - 6 months through 4 years of age
  - [Pfizer COVID-19 EUA Fact Sheet for Recipients and Caregivers](#) - 6 months through 4 years of age

- **COVID-19 Vaccines**
- [Emergency Use Authorization for Vaccines Explained](#)

---

**Key Summary and Actions Items**

- 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 eight weeks after the second dose in individuals 6 months through 4 years of age.

- **The ACIP is meeting to provide clinical considerations and the CDC director must sign the ACIP’s recommendations before Iowa healthcare providers may administer COVID-19 vaccine to these age groups.**

- The ACIP meeting is June 17-18, 2022.
  - [ACIP Agenda June 17-18, 2022](#)
  - [Webcast Link](#)