

COVID-19 Vaccine Information Brief

June 17, 2022

Changes to the document from the previous version are highlighted in yellow.

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](#)
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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](#)