

Health Advisory

COVID-19 Vaccine Updates: Pediatric Immunization for Children Ages 5-11 November 5, 2021

SUMMARY POINTS

- Emergency Use Authorization of Pfizer-BioNTech COVID-19 vaccine has been expanded to include children ages 5-11 years.
- The FDA authorized Pfizer-BioNTech COVID-19 vaccine for children uses a pediatric formulation (orange cap) with a dose of 10µg (0.2mL following dilution). 2 doses should be administered 21 days apart.
- The benefits of immunization of children ages 5-11 with the Pfizer-BioNTech COVID-19 vaccine outweigh the risks of vaccine related myocarditis in this age group.
- The Pfizer-BioNTech COVID-19 vaccine may be co-administered with non-COVID-19 vaccines.
- Children ages 5-11 with a history of multisystem inflammatory syndrome (MIS-C) may be immunized with the Pfizer BioNTech COVID-19 vaccine.

Pediatric Immunization

On October 29th, 2021, the Food and Drug Administration (FDA) expanded Emergency Use Authorization (EUA) for Pfizer-BioNTech COVID-19 vaccine to children aged 5-11 years. On November 2nd, 2021, the Advisory Committee on Immunization Practices (ACIP) made an interim recommendation for use of the vaccine in this age group for prevention of COVID-19. COVID-19 primary vaccination is recommended for everyone aged 5 years and older, regardless of a history of underlying medical conditions, history of SARS-CoV-2 infection, or seropositivity.

Safety, immunogenicity, and reactogenicity data were similar to that of young adults ages 16-25 years.

Dosing and Interval

- Children should receive the age-appropriate vaccine formulation **regardless of their size or weight**. Children should receive the vaccine dosage and formulation based on their age on the day of vaccination with each dose.
- The pediatric formulation of the Pfizer-BioNTech COVID-19 vaccine is available in an orange capped vial. The dose is 10µg with an injection dose of 0.2mL following dilution with 1.3 mL of 0.9% Sterile Sodium Chloride Injection, USP. The use of the adolescent/adult formulation of the Pfizer-BioNTech COVID-19 (COMIRNATY) vaccine (purple cap) is **not** acceptable for pediatric recipients ages 5-11.
- Children ages 5-11 should receive two doses of the Pfizer-BioNTech COVID-19 pediatric formulation, at least 21 days apart. An additional primary dose or booster dose is not recommended.

Expected Side Effects

- Children may experience fewer side effects following COVID-19 vaccination than adolescents or young adults. Children with evidence of prior infection may have fewer side effects than those without evidence of prior infection. Expected side effects include:
 - Local: pain, swelling, erythema at the injection site
 - Systemic: fever, fatigue, headache, chills, myalgia, arthralgia, lymphadenopathy
- Routine antipyretic or analgesic medications can be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate.
 - In general, Aspirin is **not** recommended for use in children and adolescents ≤18 years due to risk of Reye's syndrome.

Possible Risk of Myocarditis

Myocarditis is a rare, serious adverse event that has been reported after receipt of an mRNA COVID-19 vaccine, with the highest risk currently observed in males aged 12–29 years. FDA has authorized and ACIP and CDC have recommended Pfizer-BioNTech vaccines in children aged 5 -11 years based on the determination that the benefits of COVID-19 vaccination outweigh the risk of myocarditis in this population.

Coadministration with non-COVID-19 Vaccines

The Centers for Disease Control and Prevention (CDC) has issued guidance that all COVID-19 vaccines may now be administered without regard to timing of other (non-COVID-19) vaccines. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day.

When deciding to coadminister other vaccine(s) with a COVID-19 vaccine, providers should consider the following for a patient:

- Risk of becoming behind on recommended vaccines
- Risk of vaccine-preventable disease
- Reactogenicity profile of the vaccines

If multiple vaccines are administered at a single visit, administer each injection in a different injection site, according to recommendations by age.

- Separate injection sites by 1 inch or more.
- For older children (≥ 11 years), the deltoid muscle can be used.
- For younger children (5–10 years), if more than 2 vaccines are injected in a single limb, the vastus lateralis muscle of the anterolateral thigh is the preferred site because of greater muscle mass.

History of MIS-C

- Children and adolescents with a history of multisystem inflammatory syndrome (MIS-C) may be immunized with the Pfizer BioNTech COVID-19 vaccine.
- The benefits of COVID-19 vaccination for children and adolescents with a history of MIS-C are likely to outweigh a theoretical risk of an MIS-like illness or the known risks of COVID-19 vaccination for people who meet all of the following criteria:
 - 1) Clinical recovery has been achieved, including return to normal cardiac function;
 - 2) It has been ≥ 90 days since their diagnosis of MIS-C;
 - 3) They are in an area of high or substantial community transmission of SARS-CoV-2, or otherwise have an increased risk for SARS-CoV-2 exposure and transmission;
 - 4) Onset of MIS-C occurred before any COVID-19 vaccination.

COVID-19 vaccination may also be considered for children with a history of MIS-C who do not meet all the prior criteria.

- Experts view clinical recovery, including return to normal cardiac function, as an important factor when considering COVID-19 vaccination.
- Additional factors when considering individual benefits and risks may include:
 - 1) An increased personal risk of severe COVID-19 (e.g., age, underlying conditions)
 - 2) Timing of immunomodulatory therapies

Additional Information:

- [nCoV template PPT GEN PUB \(cdc.gov\)](#)
- [Pfizer-Pediatric-Reference-Planning.pdf \(cdc.gov\)](#)
- [Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC](#)
- [Comirnaty and Pfizer-BioNTech COVID-19 Vaccine | FDA](#)

Guidance adapted from the above references.