COVID-19 Vaccination in Adolescents and Children

The Pfizer-BioNTech COVID-19 vaccine is the only COVID-19 vaccine currently available for children and adolescents aged 5 years and older. The Centers for Disease Control and Prevention (CDC) recommends that children ages 5 to 11 years receive two doses (10 mcg; 0.2 mL each) 21 days apart. Adolescents (and adults) ages 12 years and older should receive two doses (30 mcg; 0.3 mL each) 21 days apart. Children and adolescents should receive the age-appropriate vaccine type regardless of their size or weight. This resource is designed to help pharmacists vaccinate adolescents and children against COVID-19 safely and effectively.

Quick Links

- CDC's COVID-19 Vaccination for Children 5 Through 11 Years Old
- CDC's How Schools Can Support COVID-19 Vaccination
- CDC's How to Talk With Parents and Caregivers About COVID-19 Vaccination
- CDC's COVID-19 Vaccines for Children and Teens
- CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States—Vaccination of Children and Adolescents
- FDA's Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers and for Recipients and Caregivers

Pfizer-BioNTech COVID-19 Vaccine Formulations		
Formulation	**Adolescent/Adult (Ages ≥12 years)**	**Pediatric (Ages 5–11 years)**
Vial Cap Color	Purple transitioning to Gray	Orange
Fact Sheet (EUA)	For Healthcare Providers For Recipients and Caregivers	For Healthcare Providers For Recipients and Caregivers
Administration		
Administer	Intramuscular (IM)	Intramuscular (IM)
Dose	**30 mcg** (0.3 mL each)	**10 mcg** (0.2 mL each)
Amount of Diluent Needed per Vial	Purple Cap: 1.8 mL of 0.9% Sodium Chloride Injection Gray Cap: do not dilute	1.3 mL (0.9% Sodium Chloride Injection)
Doses per Vial (After Dilution)	Purple Cap: 6 Gray Cap: 6	10
Schedule	Two-dose series	Two-dose series
Recommended Interval	3–8 weeks after first dose*	3 weeks (21 days) after first dose

COVID-19 Vaccination in Adolescents and Children (continued)

Administration *continued*		
Additional Dose	Recommended for moderately or severely immunocompromised individuals **≥12 years old** at least 4 weeks after second dose	Recommended for moderately or severely immunocompromised individuals **5-11 years old** at least 4 weeks after second dose
Booster Dose	Recommended for individuals **≥12 years** of age	Recommended for individuals **5-11 years** of age
Storage**		
Ultra-Low Temp. (ULT) Freezer	9 months	6 months
Freezer	2 weeks	Not recommended
Refrigerator	1 month	10 weeks
Expiration	Vial is **labeled with EXPIRY date**; vials with expiry date of July 2021–February 2022 may remain in use 3 months beyond printed date if stored in ULT freezer	Vial is **labeled with MANUFACTURE date**, NOT expiration date; product expires 6 months after date of manufacture if stored in ULT freezer

** An 8-week interval in the primary series may be optimal for some people ages 5 years and older, and especially for males ages 12 through 39 years, who are not moderately or severely immunocompromised, and for whom there is not increased concern about community transmission or severe disease.*

***Temperature Key:*

Ultra-Low Frozen Temperature: -90°C to -60°C (-130°F to 76°F)

Frozen Temperature: -25°C to -15°C (-13°F to 5°F)

Refrigerated Temperature: 2°C to 8°C (35°F to 46°F)

Why is a different Pfizer-BioNTech COVID-19 vaccine formulation needed to vaccinate children ages 5 to 11 years?

The pediatric-indicated (orange cap) Pfizer-BioNTech vaccine is the same vaccine proven safe and effective in adolescents/adults (purple or gray cap). Children ages 5 to 11 years require a smaller dose of the Pfizer-BioNTech COVID-19 vaccine based on the safety, tolerability, and immunogenicity profiles in children studied. If the adolescent/adult-indicated vaccine was used to prepare doses for children 5 to <12 years old, the resulting injection volume for the 10 mcg dose would be 0.1 mL. This injection volume is considered too small for an intramuscular (IM) injection and has not been studied, and therefore should not be prepared or administered in this manner. The pediatric-indicated vaccine (orange cap) is designed to deliver the 10 mcg dose in a larger injection volume of 0.2 mL, which is the authorized and recommended product.

COVID-19 Vaccination in Adolescents and Children (continued)

Is the Pfizer-BioNTech COVID-19 vaccine FDA-approved for children ages 5-11 years old?

No. Under an Emergency Use Authorization (EUA), FDA **authorized the emergency use** of the Pfizer-BioNTech vaccine in individuals between the ages of 5-15 years old (5-11 years old for the pediatric-indicated vaccine, and 12-15 years old for the adolescent/adult-indicated vaccine). When a product is licensed it becomes an FDA-approved product. The Pfizer-BioNTech COVID-19 branded vaccine (Comirnaty) is only **FDA-approved** for individuals 16 years and older and contains the same ingredients as the Pfizer-BioNTech COVID-19 vaccine authorized under emergency use for individuals 12 years and older.

Who is authorized to order and administer the Pfizer-BioNTech COVID-19 vaccine at the pharmacy?

The U.S. Department of Health and Human Services expanded COVID-19 vaccination authority under the Public Readiness and Emergency Preparedness (PREP) Act for pharmacists, pharmacy technicians, student pharmacists and interns, and retired or inactive pharmacists and interns nationwide during the public health emergency. Each of these pharmacy team members may administer the COVID-19 vaccines to persons 3 years of age and older, as recommended. *Pharmacists can order the Pfizer-BioNTech vaccine for eligible persons ages 5 years and older.* No prescription is required. For more information, refer to "Authority to Immunize During COVID-19" in APhA's Know the Facts practice resource library.

What evidence is available to support the safety and efficacy of the Pfizer-BioNTech COVID-19 vaccine in adolescents and children?

Studies show that vaccinating children ages 5 to 11 years with the Pfizer-BioNTech vaccine is safe and effective at preventing asymptomatic/mild infection. The vaccine was found to be 90.7% effective in preventing COVID-19 and the vaccine's safety was studied in 3,100 children finding no serious side effects. CDC reports a study of 2,200 participants ages 12 to 15 years that found the Pfizer-BioNTech COVID-19 vaccine was 100% effective in preventing COVID-19. No safety concerns were identified.

Why might an 8-week interval between the first and second dose be beneficial for adolescents 12 years and older (through age 64 years) — who are not moderately or severely immunocompromised, and for whom there is not increased concern about community transmission or severe disease?

Recent safety and effectiveness data illustrate that a longer time interval between the first and second mRNA COVID-19 vaccine dose gives the body a chance to build a stronger immune response, increasing the effectiveness of these vaccines, and offering individuals greater protection against COVID-19. A longer interval between primary doses can also help lower the rare risk of myocarditis and pericarditis following vaccination. Although rare, some cases have been reported—mostly among adolescent and young adult males—after receiving the Pfizer-BioNTech or Moderna vaccines.

COVID-19 Vaccination in Adolescents and Children (continued)

How should the Pfizer-BioNTech COVID-19 vaccine be administered to adolescents and children?

Both the adolescent/adult- and pediatric-indicated Pfizer-BioNTech COVID-19 vaccines are administered intramuscularly (IM). Smaller needle lengths may be needed for younger patients. Reference CDC's Vaccine Administration: Needle Gauge and Length resource for a complete summary of the recommended needle gauges and lengths for patients based on age.

APhA's application-based learning activity, Pharmacy-Based Immunizations for Pediatric Patients, provides a thorough review of topics related to immunizing pediatric patients, including parent and patient preparation and immunization administration techniques for children.

Should other vaccines be coadministered with the Pfizer-BioNTech COVID-19 vaccine?

All authorized COVID-19 vaccines, including the Pfizer-BioNTech COVID-19 vaccine, may now be administered without regard to timing of vaccine administration with other vaccines. This includes simultaneous administration of COVID-19 vaccines and other recommended childhood and/or adult vaccines on the same day as well as administration within 14 days.

It is unknown whether the reactogenicity of COVID-19 vaccine is increased with coadministration, including with other vaccines known to be more reactogenic such as adjuvanted vaccines or live vaccines. When deciding whether to coadminister other vaccine(s) with COVID-19 vaccines, providers should consider:

- Whether the patient is behind or at risk of becoming behind on recommended vaccines.
- The patient's risk of vaccine-preventable disease (e.g., during an outbreak or occupational exposures).
- The reactogenicity profile(s) of the vaccines.

Providers should inform the patient and parent or caregiver of the potential reactions to the vaccines, duration of symptoms, and management of those effects.

What steps should vaccine providers take when administering multiple vaccines during a single visit?

If multiple vaccines will be administered during a single visit, administer each vaccine at a different injection site. For adolescents and adults, the deltoid muscle can be used for more than one intramuscular injection. Best practices for multiple injections include:

- Administer the vaccines in separate limbs, especially vaccines that may be more likely to cause a local reaction (e.g., tetanus-toxoid–containing and adjuvanted vaccines), if possible.
- Separate injection sites by 1 inch or more, if possible, when administering in the same limb.
- In situations when two or more vaccines need to be administered in the same limb for children 5 to 10 years of age, the preferred muscle is the vastus lateralis because of the larger muscle mass compared with the deltoid muscle.

APhA's Pharmacy-Based Immunizations for Pediatric Patients training program includes illustrations and video demonstrating several different approaches to identify the appropriate administration site, including the vastus lateralis in both infants and toddlers.

COVID-19 Vaccination in Adolescents and Children (continued)

How should adolescents and children be monitored after vaccination?

The post-observation time and process is the same for adolescents and children as it is for adults. Individuals with no history of allergic reaction should be monitored for 15 minutes. Adolescents and children with a history of allergic reaction should be monitored for 30 minutes.

Adolescents and children may be at increased risk of experiencing a syncopal (fainting) episode after receiving any immunization, including COVID-19 vaccine. Providers should pay particular attention to potential syncope reactions in this age group and maintain proper facility space and seating options to minimize fall risk.

What should adolescents/children and their parents or caregivers expect after vaccination?

Post-vaccination symptoms are common, such as a sore arm, redness at the injection site, fever, fatigue, headache, and chills. Children may experience fewer side effects than adolescents or young adults. For all currently authorized COVID-19 vaccines, antipyretic or analgesic medications (e.g., acetaminophen, non-steroidal anti-inflammatory drugs) can be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate. However, routine prophylactic administration of these medications for the purpose of preventing post-vaccination symptoms is not currently recommended.

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of heart lining) have been reported after mRNA vaccination in adolescents. The observed risk is highest in males 12 to 29 years of age. A report found that the risk of myocarditis or pericarditis after receipt of an mRNA COVID-19 vaccine is lower than the risk of myocarditis associated with COVID-19 infection in adolescents and adults. The symptoms of myocarditis and pericarditis include acute chest pain, shortness of breath, and palpitations. Patients who sought medical care for these symptoms responded well to medication and rest, in most cases.

There is no evidence that any vaccines, including COVID-19 vaccines, can cause female or male infertility.

Should people who have had COVID-19 infection get vaccinated?

Yes, CDC recommends vaccination regardless of whether or not a patient has already had COVID-19 infection. Substantial immunologic and an increasing body of epidemiologic evidence indicates that vaccination after infection significantly enhances protection and further reduces the risk of reinfection and one study showed that unvaccinated people who already had COVID-19 are more than two times likely than fully vaccinated people to get COVID-19 again.

What steps should parents and caregivers take to monitor children for safety related to COVID-19 vaccination?

V-safe has been updated to allow parental input and management. Parents or guardians can register their adolescents or children in v-safe and complete the health surveys on their behalf. CDC's v-safe call center follows up on reports to v-safe that include possible medically significant health events to collect additional information for completion of a Vaccine Adverse Event Reporting System (VAERS) report. A parent or guardian can enroll the adolescent or child under their v-safe profile by clinking on add a dependent.

COVID-19 Vaccination in Adolescents and Children (continued)

What steps should vaccination providers take to monitor for safety related to COVID-19 vaccination?

Vaccination providers are required to report vaccination administration errors, serious adverse events, cases of multisystem inflammatory syndrome, and cases of COVID-19 that result in hospitalization or death after administration of COVID-19 vaccine under an emergency use authorization (EUA).

Adverse events that occur after receipt of any COVID-19 vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS). Information on how to submit a report to VAERS is available at their website or by calling 1-800-822-7967.

What additional requirements should pharmacies be prepared to meet?

If the patient is 18 years of age or younger, the vaccination provider must inform the patient and/or the adult caregiver accompanying the patient of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate. The following materials were designed by APhA and others to help pharmacy teams meet this requirement:

- Well-Child Visit Brochure
- Template Referral Form for Well-Child Visit
- Well-Child Checkup Letter