



Joint Interagency Task Force on COVID-19 Vaccines

Pfizer-BioNTech COVID-19 Pediatric Vaccine Ages 5-11 years (Orange Cap)

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Pfizer-BioNTech COVID-19 Pediatric Vaccine ages 5-11 years

- The FDA further expanded the Pfizer-BioNtech COVID-19 Vaccine for Pediatrics (Orange Cap) on October 29, 2021.
- November 2, 2021 ACIP voted and CDC recommended the Pfizer-BioNtech COVID-19 Pediatric Vaccine (Orange Cap) that children 5 to 11 years old be vaccinated against COVID-19 with the Pfizer-BioNTech pediatric vaccine.
- The vaccine was nearly 91% effective preventing COVID-19 among children aged 5-11 years.

Interim Clinical Considerations for COVID-19 Vaccine in Children Ages 5-11. Dr. Woodsworth. ACIP Meeting 11-2-2021 available at <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/07-COVID-Woodworth-508.pdf>

EUA for Pfizer BIONTech COVID-19 Vaccine Pediatric (Orange Cap) available at <https://www.fda.gov/media/153714/download> and <https://www.fda.gov/media/153717/download>

Formulations and Dosing

	Formulation for ≥12-year-olds (purple cap)	Formulation for 5–11-year-olds (orange cap)
Age group	12 years and older	5-11 years
Vial cap color		
Dose (mRNA concentration)	30 ug	10 ug
Injection volume	0.3 mL	0.2 mL
Fill Volume (before dilution)	0.45 mL	1.3 mL
Amount of Diluent* Needed per vial	1.8 mL	1.3 mL
Doses per Vial	6 (after dilution)	10 (after dilution)

*Diluent: 0.9% sterile Sodium Chloride Injection, USP (non-bacteriostatic; DO NOT USE OTHER DILUENTS)

Modified from <https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Pediatric-Reference-Planning.pdf>

Formulations and Dosing

	Formulation for ≥12-year-olds (purple cap)	Formulation for 5–11-year-olds (orange cap)
Storage conditions		
Ultralow temperature freezer (-90°C to -60°C)	9 months	6 months
Freezer (-25°C to -15°C)	2 weeks	N/A
Refrigerator (2°C to 8°C)	1 month	10 weeks

*Diluent: 0.9% sterile Sodium Chloride Injection, USP (non-bacteriostatic; DO NOT USE OTHER DILUENTS)
Modified from <https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Pediatric-Reference-Planning.pdf>

Formulations and Dosing

	Formulation for ≥12-year-olds (purple cap)	Formulation for 5–11-year-olds (orange cap)
Number of doses	2	2
Interval	3 weeks (21 days)	3 weeks (21 days)
Additional primary dose	Moderate and severe immunocompromise	Not recommended
Booster dose	Not recommended 12–17 years	Not recommended
	Recommended for certain groups ≥18 years*	

*Individuals 65 years and older or individuals ages 18 years and older who live in long-term care settings, have underlying medical conditions, or who work or live in high-risk settings. Mbaeyi S, Oliver SE, Collins JP, et al. The Advisory Committee on Immunization Practices' Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines — United States, 2021. MMWR Morb Mortal Wkly Rep. ePub: 29 October 2021

Other Storage and Handling

- This vaccine cannot be refrozen.
- From the time the vaccine is placed in the refrigerator, it is good for 10 weeks and this date should be written on the vial.
- Regardless of storage condition, vaccines should not be used after 6 months from the **date of manufacture** printed on the vial and cartons
- Vials should be discarded 12 hours after dilution. Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in the current EUA supersedes the number of hours printed on vial labels and cartons.

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Other Clinical Information

- Correct Dosage is based on the child's age the day of the vaccination.
- COVID-19 primary vaccination would be recommended for everyone ages 5 years and older, **regardless of underlying medical conditions.**
- Side Effects: Anticipate fewer side effects than adolescents or adults
 - 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. Aspirin is NOT recommended in those 18 years and under due to risk of Reye's Syndrome

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Administration

- COVID-19 vaccines may be administered without regard to timing of other vaccines. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day.
- 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.

Administration

- After dilution:
 - Each dose drawn must contain a white to off-white suspension with no particulate
 - Each dose must contain 0.2mL of the vaccine
 - If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2mL, discard the vial and content
 - Do not pool vaccine from multiple vials
 - The full 0.2mL dose must come from a single vial

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Selection of appropriate needle length

Age	Needle length	Injection site
3-10 years	$\frac{5}{8}$ –1" ¹	Deltoid muscle of arm (preferred)
	1–1 $\frac{1}{4}$ "	Vastus lateralis muscle of anterolateral thigh (alternative)
11-18 years	$\frac{5}{8}$ –1" ¹	Deltoid muscle of arm (preferred)
	1–1 $\frac{1}{2}$ "	Vastus lateralis muscle of anterolateral thigh (alternative)

A 5/8" needle may be used in newborns, preterm infants, and patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin.

<https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf>

Administration Errors

- Formulations of the Pfizer-BioNTech COVID-19 Vaccines are NOT interchangeable.
 - If a child ages 5–11 years inadvertently receives a 30 mcg dose for their first dose, they should receive a single age-appropriate 10 µg dose for their second dose 21 days later and should be considered as having a completed primary series.
 - If a child ages 5–11 years inadvertently receives a 30 mcg dose for their second dose, they should be considered as having a completed primary series.

Administration Errors

- If an individual aged ≥ 12 years inadvertently receives a 10 mcg dose, the dose should be repeated with the age appropriate 30 mcg dose **immediately**.
 - Exception for children who turned from 11 to 12 years in between their first and second dose and receive a second 10 mcg dose to complete their series.
- Due to the rare risk of myocarditis, males aged < 30 years may consider waiting 21 days (the recommended interval) after the erroneous dose to repeat the dose.

Vaccine Adverse Event Reporting System (VAERS)

- For reporting adverse events or administration errors for vaccines
- Must be completed if error occurs and contact WV Poison Center at 1-800-222-1222 and further instructions will be provided by Dr. Elizabeth Scharman.

Counseling

- Benefit of COVID-19 vaccination out-weighs risk in ages 5-11 population.
- In very rare cases, myocarditis/pericarditis (inflammation in and around the heart) have been reported after Pfizer-BioNTech COVID-19 vaccination of children 12–17 years, and no cases were reported in clinical trials for children 5–11 years.
- Risk of myocarditis/pericarditis after getting an mRNA COVID-19 vaccine is lower than the risk of myocarditis from getting COVID-19 disease in adolescents and adults.

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EUA

- New EUA for providers located [here](#) and on CDC website
- New EUA for Patients and Caregivers located [here](#) and on CDC website
- EUA for Patients and Caregivers must be provided to Parent with each vaccine given (or electronic version)
- Note: items for this pediatric vaccine are color coded ORANGE

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Tips for Preparing Children for Vaccination

- Resources available at [HealthyChildren.Org](https://www.healthychildren.org) & CDC
- Make a plan, talk before
 - Remind the child that vaccines can keep them healthy
 - Be honest. Provide support.
 - Avoid telling scary stories or making threats about vaccination
- Help the child feel in control:
 - Use words that create a positive story about their experience
 - Let them know you understand their worries
 - Make the child feel heard
 - Don't apologize
 - Provide a good reason why they need the vaccine

Tips for Preparing Children for Vaccination

- Resources available at HealthyChildren.Org & CDC
- Plan for vaccination
 - Comfort
 - Consider numbing creams and sprays
 - Vibration
 - Distraction
 - Take
 - deep breaths

Enroll to be a COVID-19 Vaccine Provider

COVID-19 Vaccine Program Enrollment and Participation Steps:

1. Email CovidVaccinationProg@wv.gov requesting enrollment.
2. Complete the WVSIS Provider Agreement and WVSIS New User Enrollment forms (available at <https://wvruralhealth.org/event/virtual-qa-session-on-how-to-enroll-in-the-wv-covid-19-vaccine-program/>)
3. Receive an email with link to complete the CDC COVID-19 Vaccine Agreement form.
4. Receive a link to register with Vaccine Finder (Inventory reporting is required).
5. Providers who are enrolled in the Vaccines for Children (VFC) program will use the same provider identification number (PIN) to for ordering and reporting.
6. At this time, vaccine ordering is through the electronic immunization management system (EIMS) which is accessible at eimshelpdesk@wv.gov.

Enroll to be a COVID-19 Vaccine Provider

COVID-19 Vaccine Program Enrollment and Participation Steps:

7. Vaccine orders must be picked up at vaccine depots. They are not drop-shipped at this time.
8. Vaccines come with administration supplies including needles, syringes, prep pads, face shields and surgical masks.
9. Providers may bill insurance and other 3rd party payers for administration of vaccine but may not charge out-of-pocket fees.
10. Some wastage is inevitable since all COVID vaccine presentations are multidose vials without preservatives:
 - Moderna vaccine vials must be use 12 hours after the first puncture
 - Pfizer and J&J vaccine vials must be used within 6 hours of first puncture
 - Unused doses must be reported on the Unused Doses Report Form
11. Vaccine administrations must be reported to WVSIS just as other vaccinations. Most electronic medical records systems facilitate documentation and electronic reporting of COVID-19 vaccines.

Thank you -- Questions

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