

COVID-19 Vaccines for 5- to 11-Year-Olds: WHAT WE KNOW NOW

Please join us for two webinars

FRIDAY, OCTOBER 29TH & NOVEMBER 5TH

10:00 AM - REGISTER AT [ILLINOISAAP.ORG/EVENTS](https://illinoisAAP.org/events)

Updates on the vaccine rollout, timelines, ordering information for providers in Illinois *and* Chicago, and the clinical updates/guidance available at the time of these events.

Illinois Chapter, American Academy of Pediatrics – Illinois Department of Public Health
Chicago Department of Public Health – Illinois Academy of Family Physicians

Pediatric COVID-19 Vaccines: What We Know Now

Heidi Clark

Division Chief, Infectious Diseases

Karyn Lyons

Section Chief, Immunizations

October 29, 2021

Information current as of 10/28/2021

- Information shared is most up to date information we have from CDC.
- Information is subject to change, based on EUA issuance, ACIP and CDC recommendations, and evolving CDC guidance
- IDPH will continue to provide information to providers through SIREN alerts and webinars

Timeline for pediatric (5-11) authorization

- VRBPAC meeting has occurred on 10/26
- ACIP meeting 11/2-11/3
- Anticipated first date of pediatric (5-11) vaccination 11/4/21
- Preordering has begun. Vaccines can be ordered through I-CARE in 100 dose increments.
- Pre-orders in increments of 300 doses that were approved prior to 10/25/21 will be shipping soon.
- Pre-orders placed later or in 100 or 200 dose increments are expected to ship after November 8th, but earliest shipping dates are yet to be determined.
- Vaccine won't ship until EUA issuance
- Vaccine cannot be administered until ACIP/CDC recommendations are issued

Pfizer Pediatric Formulation Packaging



- Pediatric vials come packaged in cartons of 10 vials each.
- Vials come with a distinctive **orange cap, orange striping on the label, and orange striping on the carton.**
- Box dimensions: 37mm x 47mm x 89 mm.



Note: the Adult/ Adolescent formulation (purple cap) should not be used to vaccinate children 5 through 11 years of age.

Pfizer-BioNTech COVID-19 Vaccines

PRELIMINARY – SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION/APPROVAL

Description	Current Adult/Adolescent Formulation (1170 and 450 packs)	Future Pediatric Formulation
	<i>Dilute Prior to Use</i>	<i>Dilute Prior to Use</i>
Age Group	12 years and older	5 to <12 years**
Vial Cap Color	PURPLE 	ORANGE 
Dose	30 mcg	10 mcg
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 doses per vial (after dilution)	10 doses per vial (after dilution)
Storage Conditions		
ULT 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)

**The vaccine is currently under emergency use authorization review by the Food and Drug Administration (FDA) for children 5 to <12 years old

Q: Can the current adult/adolescent formulation (purple cap) be used to vaccinate children 5 to <12 years old once the vaccine is authorized for this age group?

A: No. For children under 12 years of age, you cannot use the current formulation and will need to use the future pediatric (orange cap) formulation.

Purple Cap – Adult/Adolescent: Authorized only for aged 12 years and older



Orange Cap – Pediatric: Future authorization for aged 5- to 12 years. A separate vaccine formulation specific for a 10mcg dose will be introduced.



NOTE: Use of the current adult/adolescent formulation (purple cap) to prepare doses for children 5 to <12 years would result in an injection volume for the 10mcg dose of 0.1mL, which is both generally considered too small for typical IM injections and has not been studied.

Pediatric vaccine shipments

- New product configuration will be 10 dose vials in packages of 10 vials (100 dose trays)
 - Minimum of 100 doses and increments of 100 doses
- Providers are encouraged to consider second dose needs when planning their orders
- Adult/adolescent Pfizer vaccine will not ship the first week pediatric vaccine is being distributed

Shippers

- Pfizer pediatric vaccine will be shipped on dry ice
- Shipping containers are smaller than the adult dose shippers
- **These shippers cannot be used for temporary storage.**
- The contents **MUST** be removed and placed in a refrigerator or ultra-cold freezer as soon as the order is received.
- Shipping boxes will continue to contain the familiar Controlant temperature monitor.
- Check the temperature monitor for any excursion warnings, turn the monitor off, and return it in the package provided.



Pfizer Pediatric Cold-Chain Storage

- The table below indicates the length of time the pediatric vials can be stored at each temperature.
- Note, the 10 weeks in the refrigerator is **not** in addition to the 6 months in the ultra-low freezer. All conditions for storage must be completed within the overall timeframe for expiration.
- Expired vaccine should be discarded regardless of storage conditions.
- Do not store Pfizer pediatric vaccine in a standard freezer.

Storage Conditions	
ULT Freezer (-90°C to -60°C)	6 months
Freezer (-25°C to -15°C)	N/A
Refrigerator (2°C to 8°C)	10 weeks

Get ready in I-CARE

- Prior to placing an order, ensure the following information is completed or updated:
 - Temperature logs for all appliances are up to date.
 - All data logger certificates of calibration are valid and not expired.
 - All temperature excursions have a vaccine incident report on file.
 - No expired vaccines are showing in the clinic's inventory.
 - The clinic's inventory in I-CARE matches the physical inventory.
 - The clinic's inventory in I-CARE is not showing any negative balances.
 - Clinic must be open at least three days a week with at least four consecutive hours a day to be able to receive a delivery. Delivery hours must be entered and updated in I-CARE, including specifying if the clinic is closed during lunch or other hours, when placing orders through I-CARE.

Pfizer COVID-19 Vaccine Medical Updates on Current & Potential New Formulations

- Pfizer Vaccines US Medical Affairs is hosting Immunization Site Training Sessions for All Providers on the Storage, Handling, & Administration for Current & Potential New Formulations of its COVID-19 vaccine.
- These sessions will be updated to reflect new information and changes as they evolve.
- Such updates will be identified at the start of each session and further explained during each presentation.

Pfizer COVID-19 Vaccine Medical Update Links

- Please click on the links below to join the sessions at the designated times.
- Weblinks for future training sessions will be provided at a later date.

Date & Time	Password
<u>Attendee link – October 29 – 12 PM ET</u>	cnRBrmGr324
<u>Attendee link – November 1 – 5 PM ET</u>	g9ZmgHaip32
<u>Attendee link – November 2 – 5 PM ET</u>	sJDZQERp325
<u>Attendee link – November 3 – 12 PM ET</u>	82qdN3PppPp
<u>Attendee link – November 4 – 12 PM ET</u>	Y4ZkXdh2bz7
<u>Attendee link – November 5 – 12 PM ET</u>	rJSpNPts332

CDC Webpage for Pediatric COVID-19 Vaccination

- CDC now has a live web page with information regarding COVID-19 Vaccination for Children 5 through 11 years of age
- Information is available for Jurisdictions, Pediatric Healthcare Providers, Pharmacists and Community Partners
- This will be updated as additional information becomes available.

[COVID-19 Vaccination for Children 5-11 Years Old | CDC](#)

Models for managing tray sizes

- Practices that are unable to utilize the number of doses distributed in a minimum order are encouraged to consider prudent inventory management:
 - Partner with other providers in a hub and spoke model
 - Utilize the Vaccine Matchmaker Tool
 - Work with your local health department to obtain smaller amounts of vaccine
- If you utilize these options, ensure you are familiar with proper cold storage and handling during transfers and complete the appropriate paperwork with IDPH so your inventory remains up-to-date
- Only transfer vaccine to providers with approved COVID-19 provider agreements (PINs start with “V”)

Preparing for rollout

- Prepare all in your practice for rollout
- Communicate with parents about expectations
- Ensure staff are equipped and trained to respond to possible severe allergic reactions
- Consider co-administration of COVID-19 vaccines with influenza and other childhood vaccines, when appropriate
- Consider offering COVID-19, influenza, or other routine vaccines, as feasible, to additional eligible persons (e.g., siblings, family members, community members) when vaccinating the pediatric population
- Plan clinics according to timelines for authorizations and shipment of vaccines
 - Consider second dose timing when scheduling clinics

Other Considerations

- COVID-19 vaccines can be administered without regard to timing
- Reminder: Providers are required to report certain adverse events following COVID-19 vaccination to VAERS and support providers in encouraging parents or guardians to enroll their children in v-safe
- Training will be required for all providers administering vaccine
- Vaccines.gov will have pediatric Pfizer listed separately from adult Pfizer
 - Please make sure to update your vaccine availability on vaccines.gov

Contact Us for Information

To enroll in I-CARE: dph.immunizations@illinois.gov