

COVID-19 Vaccine

Pediatric Vaccine Overview and

How to Order Doses
Through VOMS





Pediatric COVID-19 vaccine

Multiple vaccine manufacturers are currently developing COVID-19 vaccines for children. Pending U.S. Food and Drug Administration authorization and Centers for Disease Control and Prevention recommendations, some details about the vaccine program are still forthcoming, and additional information will be forthcoming.



Timing

- Oct. 26, 2021 U.S. Food and Drug Administration's (FDA's)
 Vaccines and Related Biological Products Advisory
 Committee (VRBPAC).
- Nov. 2-3, 2021 Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP).



Pediatric
COVID-19 Vaccine

The Pfizer-BioNTech COVID-19 Vaccine for 5 to 11-year-olds:

- Is a new product with different dosage from adult formulation.
- Has new packaging.
- Has a new national drug code (NDC).

The current product for adults and adolescents **should not** be used in children. The pediatric product should not be used for adolescents or adults.

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
	Dilute Prior to Use	Dilute Prior to Use
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



Pediatric COVID-19 Vaccine

The current Pfizer-BioNTech COVID-19 vaccine for adolescents and adults **should not** be used for children.











Storage and Handling

Pfizer-BioNTech Pediatric COVID-19 Vaccine

- Can be stored at ultra-low temperatures
 (minus 90 degrees Celsius to minus 60 degrees
 Celsius) for <u>up to 6 months.</u>
- Can be stored in refrigerator temperatures
 (2 degrees Celsius to 8 degrees Celsius) for <u>up to 10 weeks.</u>
- Punctured vial must be used within six hours.



Storage and Handling

Pfizer-BioNTech Pediatric COVID-19 Vaccine

Pending FDA authorization:

- Newly updated ultra-low shipper.
 - Smaller in size and weight.
- Each carton contains 10 multidose vials (100 doses).
 - First week's shipment will be 300 doses.
- Each vial contains 10 doses.
- Preservative-free normal saline diluent is required.
 - Included in the ancillary kit.
 - 1.3mL required for dilution.



COVID-19 Vaccine Planning

Children 5-11 years old

- Ordering will open now.
- We anticipate order submissions no later than noon Wednesday, Oct. 20, using the ImpactSIIS Vaccine Ordering Management System (VOMS).
 - o Requesting an allocation by ordering is strongly encouraged.
 - There will be future opportunities to order this pediatric COVID-19 vaccine.
 - Only plan to order if you anticipate administering pediatric vaccine to those ages 5 to 11 years old.
 - Not all providers are expected to administer vaccines to the pediatric population.
 - o VOMS is open 24 hours daily, 7 days a week.



COVID-19 Vaccine Planning

Children 5-11 years old

At this time, the minimum number of doses that can be ordered is 300.

- Future orders will be in increments of 100 doses.
- Smaller COVID-19 providers are encouraged to work with ODH to identify and form regional partnerships with other enrolled COVID-19 providers to help with equitable distribution.

Storage and Handling

COVID-19 Vaccine Temperature Monitoring Standards

Temperature Monitoring Device minimum required functionalities:

- A temperature probe or sensor.
- An active temperature display that can be easily read from outside of the unit that can show current, minimum, and maximum temperatures.
- Resettable min/max functionality.
- Alarm for out-of-range temperatures.



Storage and Handling

COVID-19 Vaccine Temperature Monitoring Standards

Daily Temperature Monitoring

Providers who store vaccine should complete and document twice-daily temperature checks for each unit each day the office is open for services. This includes weekends or special vaccine clinic days that are outside of normal business hours. This information should be documented on ODH paper temperature logs located on the <u>ODH Pandemic Provider website</u>.

For quality assurance purposes, ODH may request a copy of the facility's temperature recordings.



Ordering Vaccine

Initial orders of pediatric formulation of the Pfizer-BioNTech vaccine will not be shipped until following approval by the FDA. Doses cannot be administered until recommended by the CDC.

Generally, anticipate 7-10 days from the date your vaccine order is entered into VOMS, and when the vaccine is delivered to your facility.

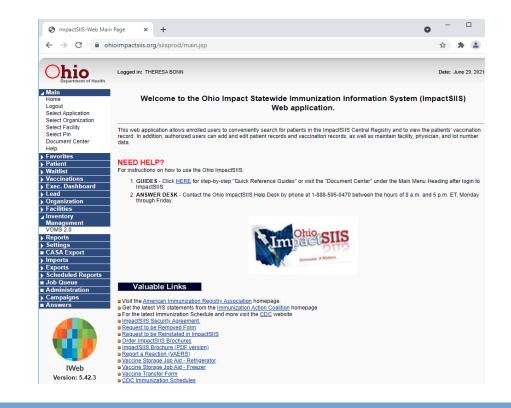


Step-by-step guide to placing order

- 1. Log into **ImpactSIIS**.
- 2. Click on **Inventory Management**.



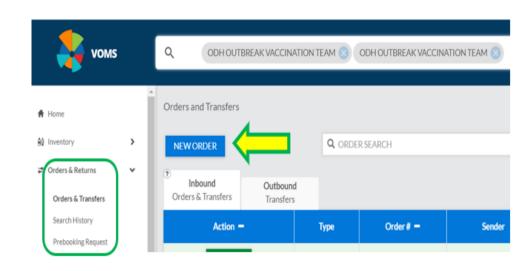
3. Click **VOMS 2.0.**



Step-by-step guide to placing order

On the **VOMS** screen:

- 1. Select site (if applicable).
- 2. Click Orders & Returns.
- 3. Click Orders & Transfers.
- 4. Click **NEW ORDER**.



It may be necessary to reconcile your inventory before ordering. Reconciling only your COVID-19 vaccine is acceptable.

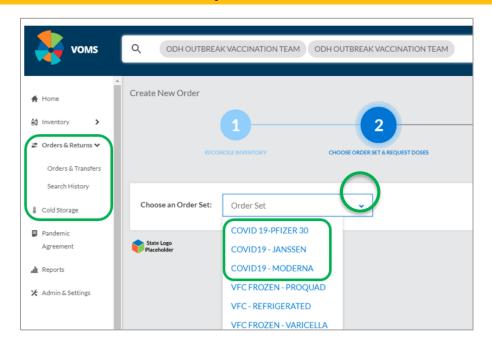




Step-by-step guide to placing order

It may be necessary to reconcile your inventory before ordering. Reconciling only your COVID-19 vaccine is acceptable.

Expand drop-down menu to Choose an Order Set.







COVID-19 vaccine order sets

In VOMS, use these COVID-19 vaccine order sets for ordering doses:

COVID-19 - Janssen

- Select this order set to request Johnson & Johnson (Janssen) vaccine.
- Minimum order quantity is 100 doses.
- Currently, this vaccine is shipped from the CDC/McKesson Distribution Center.

COVID-19 - Moderna

- Select this order set to request Moderna vaccine shipped from the CDC/McKesson Distribution Center.
- Minimum order quantity is 140 doses.
- * Moderna vials now contain 14 doses.

COVID-19 – Pfizer 30*

- Select this order set to request Pfizer vaccine repackaged through the Ohio Department of Health Receipt, Store, and Stage (RSS) warehouse.
- Adult/adolescent dose minimum order quantity is 30 doses.

COVID-19 -Pfizer RSS

- Select this order set to request Pfizer vaccine repackaged through the RSS warehouse.
- Adult/adolescent minimum order quantity is 120 doses.

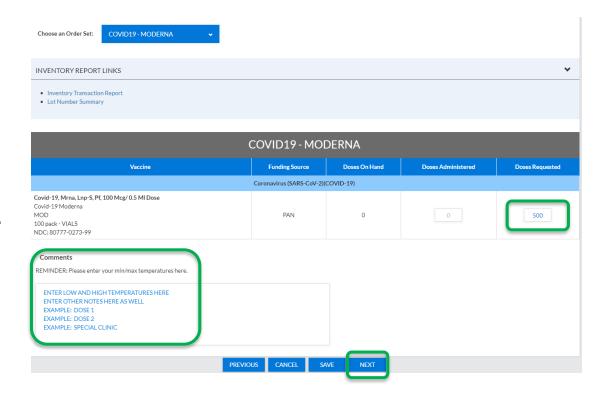
COVID-19 – Pfizer

- Select this order set to request Pfizer vaccine shipped from the manufacturer.
- Adult/adolescent minimum order quantity is 1,170 doses.
- Pediatric dose minimum order is 300 doses.



Complete order entry

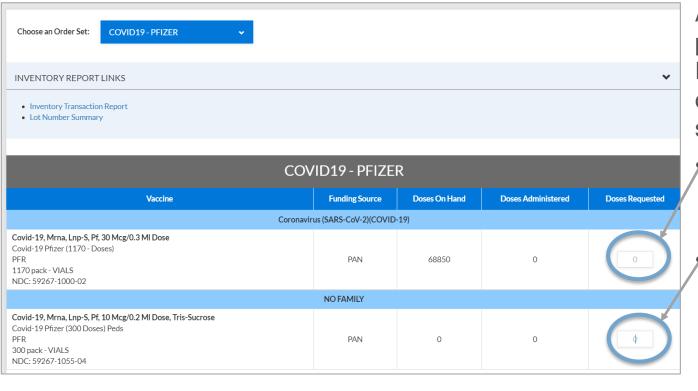
- Enter total quantity in the Doses Requested field.
- Enter high and low temperatures for your vaccine storage unit(s) since your last vaccine order in the Comments box.
 - Moderna and Pfizer orders will need freezer and refrigerator temperatures.
- Click the NEXT button.







How to order pediatric doses



Adult/adolescent and pediatric doses of the Pfizer vaccine can be ordered from the same screen:

- Enter requested adult/adolescent formulation doses.
- Then, enter how many doses you would like of the pediatric formulation.

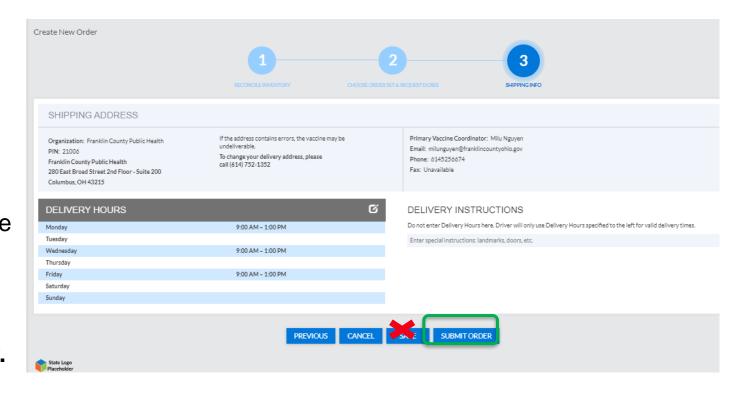


Verify shipping details, complete order

Verify the shipping address, contact information, and delivery hours.

If any of this information is incorrect, contact the ODH Provider Call Center: 1-844-963-4829.

Click Submit Order.





How to resume vaccine shipments

If your site requested to suspend shipments of COVID vaccine and you are ready to resume, please contact the ODH Provider Call Center at 1-844-90DHVAX (1-844-963-4829) or email COVIDVACCINE@odh.ohio.gov to request to unsuspend shipments.

The COVID-19 enrollment team will process the request and contact your site if additional follow-up information is needed (temperature data, etc.).

Temporary Pfizer (Adult) Shipping Halt

- During the first week of roll-out and shipment of the new pediatric formulation of the Pfizer-BioNTech vaccine, there will be a brief period of time during which shipments of adult/adolescent doses of the Pfizer-BioNTech vaccine sent directly from the manufacturer will be halted.
- VOMS will continue to be available for providers to place orders for all COVID-19 vaccines during this time.
- The RSS Warehouse will continue to redistribute the Pfizer-BioNTech adolescent/adult vaccine throughout this interval.
- Providers are encouraged to plan ahead and place orders prior to Oct. 26 for Pfizer-BioNTech adult/adolescent vaccine that may be needed in early November.



Vaccine Wastage

- ODH recognizes that current vaccine supply, demand, and administration strategies may present an increased risk of vaccine wastage.
- The goal should always be to administer COVID-19 vaccines to those who choose to be vaccinated.
- Vaccine providers should make all reasonable efforts to minimize vaccine wastage and continue to vaccinate and reduce missed opportunities.

Contact Us

Resources

 Please review the <u>ImpactSIIS</u>
 <u>Job Aids and Videos</u> page on the ODH website.

Questions

- Send future questions to impact@odh.ohio.gov.
- Contact the ODH Provider Call Center at 1-844-9ODHVAX (1-844-963-4829) or email COVIDVACCINE@odh.ohio.gov with any questions.