

Updated CDC Pediatric COVID-19 Vaccination Operational Planning Guide — Information for the COVID-19 Vaccine for Children 6 Months through 4 Years Old and/or COVID-19 Vaccine for Children 6 Months through 5 Years Old

Overview

Pfizer-BioNTech and Moderna are conducting clinical trials and data collection for COVID-19 vaccines for children ages 6 months through 4 years and 6 months through 5 years (henceforth referred to as ages 6m–4 years and 6m–5 years), respectively. Pfizer-BioNTech has begun submitting data on a three-dose primary series to FDA for an Emergency Use Authorization (EUA) application for a vaccine for children aged 6m–4 years. Moderna has also begun submitting data on a two-dose primary series for children aged 6m–5 years. This operational planning guide includes details about the anticipated Pfizer-BioNTech product and the Moderna product. This guide is intended to inform planning for all current COVID-19 vaccine programs and channels for distribution of vaccine for children aged 6m–4 years and/or vaccine for children aged 6m–5 years, should either or both vaccines receive FDA EUA and CDC recommendation. Additional information will be released as it becomes available here — <https://www.cdc.gov/vaccines/covid-19/planning/children.html>.

Please note that new information and updates have been bolded throughout the document.

FACTS

- There are approximately 20 million children aged <5 years in the United States; an additional approximately 4 million children aged 5 years have been eligible for the Pfizer-BioNTech vaccine for children aged 5–11 years since November 2021.
- FDA’s Vaccines and Related Biological Products Advisory Committee (VRBPAC) is tentatively scheduled to meet on **June 15, 2022, to discuss both the Pfizer-BioNTech vaccine for children aged 6m–4 years and the Moderna vaccine for children aged 6m–5 years**. CDC’s Advisory Committee on Immunization Practices (ACIP) is anticipated to meet within several days of VRBPAC, assuming FDA authorization; the meeting(s) will be posted here once scheduled: <https://www.cdc.gov/vaccines/acip/index.html>. ***(Note: For the remainder of this document, when used in reference to vaccines for children aged 6m–4 years or 6m–5 years, authorization refers to vaccines granted an emergency use authorization.)***
- The current products authorized for use in adults, adolescents, and children aged 5–11 years should NOT be used in children aged <5 years.
- The Pfizer-BioNTech vaccine for children aged 6m–4 years ships at -80°C, like all current Pfizer COVID-19 vaccines, and has a similar product configuration to the 5–11-year-old vaccine, but with a different color cap (maroon), different concentration (3 micrograms/0.2mL), different amount of diluent added (2.2mL), and a new national drug code (NDC). Please see the CDC document “Pfizer-BioNTech COVID-19 Vaccine Products” at <https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Pediatric->

[Reference-Planning.pdf](#) for more details. The new NDC will require additional coding and information technology accommodations, which are underway.

- **Initial shipments of the Pfizer-BioNTech vaccine for children aged 6m–4 years may state “2y to <5y” or “6m to <5y.” Vials with labels that state “2y to <5y” can be used for children aged 6m–4 years.**
 - **Pfizer-BioNTech vaccine vial labels and cartons may also state that a vial should be discarded 6 hours after the first dilution. It is anticipated the timeframe for use post-dilution will actually be 12 hours; please review the EUA Fact Sheet when it is available for confirmation.**
- The Moderna vaccine for children aged 6m–5 years ships at -20°C, like all current Moderna COVID-19 vaccines, and has a different product configuration to the adult vaccine. It has a different concentration (25 micrograms/0.25mL) and a new NDC; it does not require diluent. **The vial’s cap is blue, and the label has a magenta border.** The new NDC will require additional coding and information technology accommodations, which are underway. **A document detailing the characteristics of the Moderna vaccine for children aged 6m–5 years is being developed and will be disseminated when available.**
- The packaging configuration for both vaccine products is expected to be 10-dose vials in cartons of 10 vials each (100 doses total) with a minimum order quantity of 100 doses per product. Ancillary supplies will be provided for both vaccine products, including 1-inch needles and syringes to support 100 doses of vaccine. Diluent will be provided with ancillary supplies to support 100 doses per kit for the Pfizer vaccine.
- The PREP Act and the PREP Act Declaration issued by the Secretary of the U.S. Department of Health and Human Services authorize and provide liability protections to licensed providers and others identified in the declaration to administer COVID-19 vaccines authorized or approved by FDA, including COVID-19 vaccines authorized for administration to children. This authorization preempts state requirements that would otherwise prohibit, or effectively prohibit, these providers from administering the vaccine. The PREP Act Declaration authorizes certain providers listed in the Declaration to administer vaccines regardless of state requirements. For example, the Declaration authorizes pharmacists, pharmacy interns and pharmacy technicians nationwide to order and/or administer COVID-19 vaccines, influenza vaccines, and other vaccines authorized by FDA and recommended by CDC for children ≥3 years old (Please see: <https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf>).

ASSUMPTIONS

- As of early May 2022, more than two-thirds of Vaccines for Children (VFC) program providers were enrolled COVID-19 vaccine providers. Children ages 5–11 years who are vaccinated have also received COVID-19 vaccine at other sites, including pharmacies, where approximately one-third of vaccinated children ages 5–11 years received their COVID-19 vaccine. While many pharmacies are planning for a COVID-19 vaccination program for children under 5 years, their ability to vaccinate these children may be limited for various reasons (e.g., PREP Act Declaration authorizations). For the 6m–4

years or 6m–5 years age groups, encouraging VFC providers to enroll as COVID-19 vaccine providers and encouraging enrolled providers to administer the COVID-19 vaccine becomes even more critical to ensure access to COVID-19 vaccine as well as all other routine childhood vaccines.

- Continued coordination through jurisdictions will be needed for the Indian Health Service (IHS) facilities, Tribal and Urban Indian Health Centers, and Health Resources and Services Administration (HRSA) programs, which will continue to have directly-allocated vaccine supply at the same time as the jurisdictions.
- Similar to the COVID-19 vaccine rollout for 5–11-year-olds, jurisdictions should plan their ordering strategy now and identify priority locations to vaccinate children aged 6m–4 years or 6m–5 years.
- Shipment of Pfizer-BioNTech COVID-19 vaccine for ages 6m–4 years and/or Moderna COVID-19 vaccine for ages 6m–5 years is planned to begin once FDA issues the EUA(s), subject to independent FDA decisions. However, vaccine administration can only begin following the CDC recommendation(s).
- Doses of each vaccine will be made available under thresholds rather than allocations. This means that at the start of each new order period, doses available for ordering will be replenished up to the threshold for that order period (i.e., with each subsequent threshold, the full number of doses will be available to order). Currently, planning is for a rollout similar to the rollout of the vaccine for children aged 5–11 years, which included pre-ordering to enable vaccine to be shipped immediately following EUA.
- There will be an initial pre-EUA threshold for each vaccine followed by a threshold increase; a post-EUA threshold for each vaccine will be refreshed following EUA(s) and CDC recommendation(s) to ensure that each authorized product is able to continuously flow to sites and ensure no interruption in product availability. Details and a summary table are below.

Pre-EUA Thresholds

- Doses of each vaccine will be made available for jurisdictions, federal entities (such as IHS and HRSA), and pharmacies to pre-order. Thresholds for jurisdictions will be determined on a pro rata basis. **Threshold numbers are anticipated to be posted in Tiberius for planning purposes on June 2. Pre-orders will occur in two waves — Wave 1 and Wave 2.**
 - **Wave 1 pre-ordering will start June 3 at 10:00 AM EST and end June 8 at 9:00 AM EST.**
 - **All jurisdictions should submit a least one order for Wave 1, preferably for both vaccine products, to ensure all jurisdictions receive shipments of vaccine as product launches.**

All providers/facilities that submit orders for Wave 1 must be able to receive vaccine shipment on Monday June 20, which is the observed federal holiday for Juneteenth National Independence Day. If providers/facilities are not able to receive

vaccine shipments on June 20, they should not submit orders during Wave 1 but rather submit orders for Wave 2.

- **Wave 2 pre-ordering will start June 8 at 10:00 AM EST (with a threshold expansion) and end June 14 at 9:00 AM EST.**
- Jurisdictions should begin to prioritize which sites would be first to receive doses based on various considerations (e.g., vaccinating children at highest risk for severe COVID-19 disease; ensuring vaccine equity; feasibility of sites efficiently implementing the vaccine program; operating hours conducive to receiving and administering initial shipments). Jurisdictions should order sufficient vaccine during Waves 1 and 2 to cover the initial anticipated demand.
- Doses pre-ordered will be made available immediately following EUA.

Post-EUA Threshold

- After the EUA is issued, orders will reopen against remaining threshold.
- Orders placed after EUA will be delivered following pre-orders and will arrive in sequence, noting initial launch may stretch the usual delivery windows.
- Providers will be responsible for managing second and third doses (depending on the FDA authorization(s) and CDC recommendation(s)). Jurisdictions and clinicians should ensure that no vaccination opportunity is missed. Additional information on weekly thresholds after this threshold will be forthcoming.

The table below provides estimated delivery dates. Additional details regarding timing of delivery of vaccine shipments will be updated based on available information.

Date <small>(all subject to change)</small>	Action	Comments
<i>Pre-EUA</i>		
6/2	Thresholds posted (pro rata per jurisdiction)	<p><u>Wave 1</u></p> <ul style="list-style-type: none"> • Jurisdictions: 2 million Moderna and 2 million Pfizer • Pharmacies: 500,000 Moderna and 500,000 Pfizer <p><u>Wave 2</u></p> <ul style="list-style-type: none"> • Jurisdictions: 2 million Moderna and 2 million Pfizer • Pharmacies: 500,000 Moderna and 500,000 Pfizer
6/3	Wave 1 ordering opens at 10:00 AM EST	Sites must be able to receive product on June 20 (Juneteenth Federal Holiday) to order in Wave 1

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6/8	Wave 1 ordering closes at 9:00 AM EST	All jurisdictions should have at least one order in Wave 1
6/8	Wave 2 ordering opens at 10:00 AM EST	
6/14	Wave 2 ordering closes at 9:00 AM EST	
<i>Post-EUA</i>		
On day of EUA	Ordering reopens against remaining total threshold from Wave 1 and Wave 2	
6/20–6/24 (estimated)	Orders from Wave 1 delivered	Assumes FDA authorization(s) and CDC recommendation(s) no later than 6/18
6/23–6/29 (estimated)	Orders from Wave 2 delivered	Assumes FDA authorization(s) and CDC recommendation(s) no later than 6/18
6/27	Thresholds posted (pro rata per jurisdiction)	Jurisdictions: 4 million Moderna and 4 million Pfizer Pharmacies: 1 million Moderna and 1 million Pfizer

- Dashboards will be developed within the Tiberius application that will enable jurisdictions to view their order thresholds and optimally prioritize providers to receive initial shipments.
- The public will be directed to use www.vaccines.gov to help find providers who are offering COVID-19 pediatric vaccines. Thus, it is critical to strongly encourage all sites to turn on their public display so that their location may be displayed on www.vaccines.gov. After receiving their initial vaccine orders, providers are encouraged to report their inventory as soon as possible to assist the public seeking vaccines.
- The U.S. government and the manufacturer(s) will be providing additional training to prepare providers to administer vaccine to younger children; providers will all need to be trained.
- Vaccine administrations will be reported to the public on CDC COVID Data Tracker.

PROJECTED LAUNCH PLAN – CONSIDERATIONS FOR JURISDICTIONS

To enhance readiness to launch the 6m–4 years and/or 6m–5 years COVID-19 vaccination program and begin administering vaccine immediately following the FDA authorization(s) and CDC recommendation(s), jurisdictions should identify providers who will receive the initial doses of pediatric vaccine.

Similar to other COVID-19 vaccination program launches, including for other pediatric age groups, the first weeks of launch will require sites to be ready to meet the initial demand. Jurisdictions should create a distribution plan in coordination with local health departments

and other partners, and carefully determine which sites will receive initial vaccine product, incorporating the considerations listed below.

Jurisdictions will need to determine the sites to receive initial supplies of vaccine, balancing making vaccine accessible to all, especially where vaccine demand is expected to be high, while avoiding distributing inventory across too many sites and seeking to minimize vaccine loss. Jurisdictions and providers should not miss any opportunities to vaccinate every eligible person who presents at a vaccination site, even if it means puncturing a multidose vial to administer vaccine without having enough people available to receive each dose. The goal is an efficient rollout resulting in equitable vaccine access for the 6m–4 years and/or 6m–5 years age group in these initial weeks when demand is likely to be higher.

Considerations for selecting sites to receive the initial doses include their:

- Location and access to a range of populations (e.g., urban and rural, communities that may be disproportionately impacted by COVID-19).
- Ability to handle 100-dose product configurations, depending on whether the jurisdiction has plans in place for redistribution.
- Vaccination capacity/throughput to meet community demand.
- Ability to use all 10 doses within 12 hours once a vial is opened. Sites should consider currently configured vial size (10-dose vials) in planning and one-day timeframe when scheduling children for vaccination, especially early in the program, to optimize use of supply.
- Ability to manage inventory to ensure availability of subsequent doses in their supply chain. Jurisdictions will be responsible for managing the vaccines made available to them in their thresholds to cover second and third vaccine doses (depending on the FDA authorization(s) and CDC recommendation(s)).
- Overall readiness (e.g., staffing, training, scheduling capabilities).

PEDIATRIC READINESS CHECKLIST	
Main Theme	Key Activities for Readiness and Response
Supply and Ordering Readiness	<ul style="list-style-type: none"> <input type="checkbox"/> Determine which provider locations will receive initial vaccine supply, balancing equitable access with vaccination capacity and consideration of initial demand. Also ensure that an expanded set of providers will be able to provide equitable and convenient access to all children. <input type="checkbox"/> Finalize a list of providers and sequence of provider activation for the first week of vaccine deliveries. Jurisdictions will be submitting pre-orders for providers to facilitate delivery of initial orders. <input type="checkbox"/> Review CDC and manufacturer materials regarding product configuration, shipping, storage, dosing, dosing intervals, and adverse event profiles as they become available.

	<ul style="list-style-type: none"> <input type="checkbox"/> Optimize vaccine use by ordering additional supply responsibly to minimize unnecessary accumulation of inventory and wastage while also ensuring no vaccination opportunity is missed. <input type="checkbox"/> Manage and accurately report on-hand product inventory to inform tracking near-expiry and redistribution.
<p>Provider Readiness</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Enroll an adequate network of providers to ensure equitable access across all pediatric populations: <ul style="list-style-type: none"> <input type="checkbox"/> Identify VFC providers who are not yet COVID-19 vaccination providers and facilitate their enrollment, especially providers who can fill a geographic gap in access and providers who care for children from racial and ethnic minority groups or other communities that may be disproportionately impacted by COVID-19. This is especially important for children <3 years, who generally will not be vaccinated in pharmacies but rather in primary care clinics. <input type="checkbox"/> Reach out to tribal nations within the respective areas for involvement in planning efforts. <input type="checkbox"/> Identify and facilitate enrollment of providers who frequently care for children with disabilities or special healthcare needs (e.g., children’s hospitals, pediatric subspecialty clinics). <input type="checkbox"/> Prepare enrolled providers to receive pediatric COVID-19 vaccine: <ul style="list-style-type: none"> <input type="checkbox"/> Develop a plan to identify if or when additional sites may be needed to increase vaccination capacity for the 6m–4 years or 6m–5 years age group, especially during the initial weeks of the vaccination program when demand may be high. <input type="checkbox"/> Disseminate training and communication materials (e.g., preferred anatomical sites of vaccination in this age group) to healthcare providers, especially those who do not routinely care for this age group. <input type="checkbox"/> Remind enrolled providers to make immunization information system (IIS) changes as needed to allow for the 6m–4 years or 6m–5 years age group. <input type="checkbox"/> Remind enrolled providers to prepare scheduling systems and bolster capacity for their call center and website, as needed, to handle additional volume. <input type="checkbox"/> Ensure providers or other on-location staff are equipped and trained to respond to possible severe allergic reactions, like anaphylaxis, especially in the very young age groups where equipment and medication dosing may be different.

	<ul style="list-style-type: none"> <input type="checkbox"/> Ensure providers are prepared to recommend and co-administer COVID-19, influenza, and other childhood vaccines as appropriate to ensure children are up to date on recommended vaccines. <input type="checkbox"/> Encourage providers to consider offering the vaccine for children aged 6m–4 years or 6m–5 years who are not their patients and to turn on their public display so that their location may be displayed on www.vaccines.gov. <input type="checkbox"/> Encourage providers to consider offering COVID-19, influenza, or other routine vaccines, as feasible, to additional eligible persons (e.g., siblings, family members, community members). <input type="checkbox"/> Reinforce that providers are required to report certain adverse events following COVID-19 vaccination to the Vaccine Adverse Event Reporting System (VAERS) and support providers in encouraging parents or guardians to enroll their children in v-safe. <input type="checkbox"/> Routinely evaluate the adequacy of the provider network, identifying gaps and whether additional vaccination locations (e.g., VFC providers, local public health departments, temporary vaccination clinics, FQHCs, rural health clinics) may be needed to further increase equitable access and ensure vaccine equity. <input type="checkbox"/> Encourage providers who are not able to offer COVID-19 vaccination to refer their patients to nearby vaccination providers.
<p>Information Technology Systems, Reporting and Monitoring</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Ensure electronic systems, including IISs, are prepared to report and track pediatric vaccine administration. <input type="checkbox"/> Remember that the Special Project Provider (COVID-19 Providers) label is required for COVID-19 vaccine ordering. Inclusion of this flag on the provider record indicates that the jurisdiction has signed the agreement with the provider to receive COVID-19 vaccines. <input type="checkbox"/> Leverage Tiberius dashboards to help plan for an appropriate network of pediatric providers that ensures access by all children. <input type="checkbox"/> Once the vaccination program begins, continue to leverage Tiberius dashboards to monitor the program.
<p>Communications</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Create a communication plan that outlines strategies, audiences, and products that will be used to promote COVID-19 vaccination of children aged 6m–4 years and/or 6m–5 years. <input type="checkbox"/> Understand existing data on parent/guardian knowledge, attitudes, and perceptions regarding COVID-19 vaccination (including co-administration with influenza and routine childhood vaccines) in terms of demand, provider types, and locations where vaccination would be preferred, and anticipate timing of

	<p>when parents/guardians would be interested in getting children vaccinated. Share these data with local jurisdictions and partners to help shape messages.</p> <ul style="list-style-type: none"><li data-bbox="532 317 1382 541">❑ Develop communications products for providers, pharmacies, and the public that align with federal messaging and ensure communication materials are culturally and linguistically appropriate. Resources to promote COVID-19 vaccination for children are available at https://www.cdc.gov/vaccines/covid-19/planning/children/resources-promote.html.<li data-bbox="532 552 1382 695">❑ Leverage partnerships (e.g., American Academy of Pediatrics [AAP] and American Academy of Family Physicians [AAFP] Chapters) to help mobilize providers and promote vaccination messaging to families.<li data-bbox="532 705 1430 848">❑ Engage and educate partners and trusted messengers (e.g., healthcare professionals, community leaders, early childhood care and education providers, school administrators, faith leaders and faith-based organizations) as soon as possible.
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