UPDATED: September 20, 2022

UPDATED: CDC Fall Vaccination Operational Planning Guide

Information for the Fall Vaccine Campaign, Including Upcoming Pediatric Bivalent COVID-19 Vaccine as Boosters for Children Aged 5-11 Years

Overview and Background

On June 28, 2022, FDA's independent experts on the Vaccines and Related Biological Products Advisory Committee (VRBPAC) met to publicly discuss whether a change to the current vaccine strain composition of COVID-19 vaccines for booster doses is necessary for the 2022 fall and winter seasons. The advisory committee voted in favor of including a SARS-CoV-2 Omicron component in COVID-19 vaccines that would be used for boosters in the United States beginning in fall 2022. FDA subsequently clarified intent to authorize bivalent boosters including a BA.4/5 valence specifically.

On August 31, 2022, FDA amended the emergency use authorizations (EUAs) of the Moderna COVID-19 vaccine and the Pfizer-BioNTech COVID-19 vaccine to authorize bivalent formulations of the vaccines for use as a single booster dose at least two months following the last primary series dose or booster. CDC's Advisory Committee on Immunization Practices (ACIP) met on September 1, 2022 and voted to recommend the use of bivalent vaccines as boosters. CDC endorsed ACIP's recommendations for the use of updated COVID-19 boosters from Pfizer-BioNTech for people aged 12 years and older and from Moderna for people aged 18 years and older.

At publication of this guide, bivalent COVID-19 vaccines are authorized as a single booster dose only in people who have completed a primary vaccination series. Currently, anyone aged 12 years or older who has completed at least a primary series is eligible for a bivalent booster, regardless of number or type of prior booster doses received so long as at least two months have passed since their last COVID-19 vaccine dose. In addition, monovalent mRNA COVID-19 vaccines are no longer authorized as booster doses for individuals 12 years of age and older. Monovalent boosters are currently authorized and recommended for children aged 5-11 years and will remain available to this group until age-appropriate bivalent boosters are authorized and recommended.

If authorized by FDA, CDC anticipates a recommendation for bivalent COVID-19 vaccine as a booster for pediatric age groups in early to mid-October. Bivalent products expected to be under consideration include the bivalent Pfizer-BioNTech vaccine for children aged 5-11 years and bivalent Moderna vaccine in children aged 6-17 years, for those individuals who have already received their primary vaccine series.

It is expected that if bivalent boosters are authorized for individuals aged 5 years and older as a booster, monovalent mRNA COVID-19 vaccines may no longer be authorized as booster doses. Providers should review any FDA and CDC guidance for bivalent vaccine in children aged 5 years and older, since bivalent vaccines may be the only authorized and recommended COVID-19 boosters for this age group. At this time, it is expected that monovalent vaccines will remain appropriate for primary series for this age group.

At publication of this guide, the U.S. Government (USG) has procured over 170 million doses of bivalent COVID-19 vaccine for distribution and administration. This is part of a planned fall and early winter campaign that will include primary (monovalent) and booster (bivalent) vaccines intended to maximize availability and uptake across age groups to ensure population protection against circulating strains.

It is expected that many COVID-19 vaccination providers will offer bivalent vaccines, but not all providers are expected to continue carrying primary series COVID-19 vaccines. Providers planning to continue offering primary series COVID-19 vaccines will need to store both original (i.e., monovalent vaccine) and updated (i.e., bivalent vaccine) formulations.

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BIVALENT COVID-19 VACCINE PRODUCTS

The USG has purchased enough bivalent vaccine doses to ensure a robust and complete national booster vaccination campaign through the fall and early winter. The new bivalent COVID-19 vaccines have the same storage and handling parameters as the original vaccine products:

Pfizer-BioNTech COVID-19 Vaccines

- Ultra-cold freezer storage (-90°C to -60°C) until expiry
- NO FREEZER STORAGE
- Refrigerate (2°C to 8°C) up to 10 weeks without puncturing
- Pfizer-BioNTech bivalent COVID-19 vaccine for individuals aged 12 years and older:
    - Packaged in 6-dose vials in cartons of 10 vials each (60 doses total)
    - Does not require a diluent
    - Minimum order quantity is 300 doses
- Pfizer-BioNTech bivalent COVID-19 vaccine for children aged 5-11 years and older is expected to have the following characteristics:
    - Packaged in 10-dose vials in cartons of 10 vials each (100 doses total)
    - Requires diluent (note: awardees will not be able to opt out of receiving ancillary kits)
    - Minimum order quantity of 100 doses
    - Vial with an orange cap similar to the existing Pfizer-BioNTech product for this age group, but with a label that identifies it as a bivalent booster
- **Once punctured, each vial must be used within 12 hours.**

Moderna COVID-19 Vaccines

- NO ULTRA-COLD FREEZER STORAGE
- Freezer storage (-50°C to -15°C) until expiry
- Refrigerate (2°C to 8°C) up to 30 days without puncturing
- Moderna bivalent COVID-19 vaccine is packaged in 5-dose vials in cartons of 10 vials each (50 doses total), with a minimum order quantity of 100 doses
- The same vial (dark blue cap, gray border) and presentation for Moderna is expected to be used for all authorized age groups (people aged 6 years and older), but volume and dosage expected to differ by age:
    - Adolescents aged 12-17 years: same volume and dosage as for adults aged 18 years and older
    - Children aged 6-11 years: half the volume and dosage as for adults aged 18 years and older (drawn from the same vial). i.e., one vial yields double the number of doses when used for 6–11-year-olds as when used for people aged 12 years and older
- Moderna bivalent COVID-19 vaccine does not require diluent
- **Once punctured, each vial must be used within 12 hours.**

Ancillary Kits

Ancillary supplies will be provided, including a variety of 1-inch and 1.5-inch needles and syringes. Orders of bivalent Moderna COVID-19 vaccine for children aged 6-11 years, if authorized, will be sent with two ancillary kits per minimum dose order to accommodate double the number of doses provided in each vial. Upon Moderna authorization, providers will need to specify pediatric intent within their vaccine order process to receive the appropriate ancillary kit. An ancillary opt-out continues to be available for all non-diluent kits. (Note, Pfizer-BioNTech bivalent COVID-19 vaccine for children aged 5-11 years is expected to require diluent, so awardees will not be able to opt out of receiving ancillary kits.)

- For Awardees, opt-out instructions can be found in the VTrckS library at: https://vtrcks-library.cdc.gov/gm/folder-1.11.17315
- For Federal Agencies/Commercial Partners, opt-out functionality is available in VPoP.

CURRENT STATE OF VACCINE DISTRIBUTION

Doses of bivalent vaccines have been 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).

Pre-ordering enables COVID-19 vaccines to be shipped immediately following EUA. Pre-ordering for Pfizer-BioNTech bivalent COVID-19 vaccine for individuals aged 12 years and older and Moderna bivalent COVID-19 vaccine for individuals 18 years and older ended on August 30, 2022.

A post-EUA threshold top-off for Pfizer-BioNTech bivalent COVID-19 vaccine for individuals aged 12 years and older went into effect September 8, 2022. A post-EUA threshold top-off for Moderna bivalent COVID-19 vaccine is expected to go into effect later in September.

UPDATED LAUNCH PLAN: BIVALENT VACCINES FOR PEDIATRIC GROUPS

There will be no pre-order period for Moderna bivalent vaccine for children aged 6-11 since this product will already be in the field. However, jurisdictions should take into account sites that are not currently administering Moderna, but who plan to administer Moderna to children aged 6-11 years, as these sites will need to order vaccine specifically for this group. Bivalent Moderna vaccines are available to order against current thresholds. Upon Moderna authorization, providers will need to specify pediatric intent within their vaccine order process to receive the appropriate ancillary kit.

Doses of bivalent Moderna vaccine for children aged 6-17 years are expected to come from the same vials currently in the field that are currently used for vaccination of people aged 18 years and older. The Moderna bivalent vaccine for children aged 12-17 years is expected be the same volume and dosage as is currently authorized for individuals aged 18 years and older. The Moderna bivalent vaccine for children aged 6-11 years is expected to be half the volume and dosage that is currently authorized for adults. Although distribution of bivalent Moderna vaccine has already begun, administration to children aged 6-17 years cannot begin until after an FDA EUA and CDC recommendation.

Because bivalent Pfizer-BioNTech vaccine for children aged 5-11 years will be a new product with a unique National Drug Code (NDC), prior to EUA there will be a single pre-ordering period expected to begin at 10:00 a.m. ET on September 26, 2022, and to end on or about October 5, 2022, at 9:00 a.m. ET. Changes in this schedule are possible, so continue to monitor instructions in case the order window is changed. A post-EUA threshold for pediatric bivalent Pfizer-BioNTech vaccine will be refreshed shortly following an EUA and CDC recommendation to ensure the product is able to continuously flow to sites without interruption in product availability. Details and a summary table are below.

Jurisdictions will have the opportunity and are encouraged to order enough bivalent vaccines to meet the anticipated demands of their communities.

Pre-EUA Thresholds (bivalent Pfizer-BioNTech vaccine for children aged 5-11 years)

- Doses of bivalent Pfizer-BioNTech vaccine for children aged 5-11 years will be made available for jurisdictions, federal entities, and pharmacies to pre-order. Thresholds for jurisdictions will be determined

on a pro rata basis (based on the eligible population rather than census population). **Threshold numbers will be posted in Tiberius before pre-ordering begins for planning purposes.**

- Pre-ordering of bivalent Pfizer-BioNTech vaccine for children aged 5-11 years is anticipated to start at 10:00 a.m. ET on September 26, 2022 and to end on or about October 5, 2022 at 9:00 a.m. ET.
- Jurisdictions should begin to prioritize which sites would be first to receive doses based on various considerations (e.g., vaccinating those at highest risk for severe COVID-19 disease, such as children with certain medical conditions; ensuring vaccine equity; feasibility of sites efficiently implementing the vaccine program; operating hours conducive to receiving and administering initial shipments).
- Jurisdictions should pre-order sufficient vaccine to cover the initial anticipated demand.
- Doses that are pre-ordered will begin being processed for delivery following EUA. Expected delivery schedules will be dependent on the actual EUA date.
- Additional details regarding the timing of pre-ordering for Moderna and Pfizer-BioNTech pediatric bivalent vaccines for younger children (i.e., aged < 5/6 years) will be updated based on available information. It is anticipated that at least one bivalent vaccine for children aged 6 months to 4 years may be authorized later in the fall. Sites should plan to manage necessary freezer and refrigerator space when developing their overall fall vaccine plans.

There will be a **sufficient but finite supply** of pediatric bivalent COVID-19 vaccines, which should be directed to providers with expected demand among eligible patients. The Moderna bivalent vaccine product currently authorized for people aged 18 and older is expected be usable at the same dose for adolescents aged 12-17 years and at half the dose for children aged 6-11 years.

Due to the minimum order quantity, jurisdictions should consider internal distribution and hub and spoke operations to maximize ultra-cold freezer and refrigerator space and avoid wasting vaccine. Dashboards will be developed within Tiberius that will enable jurisdictions to view their order thresholds and optimally prioritize providers to receive initial shipments.

The public will be directed to Vaccines.gov to find providers offering pediatric bivalent COVID-19 vaccine. After receiving their initial vaccine orders, providers should report their inventory to Vaccines.gov as soon as possible following receipt of vaccine.

Post-EUA Thresholds (bivalent Pfizer-BioNTech vaccine for children aged 5-11 years)

After the EUA is issued, ordering of bivalent Pfizer-BioNTech vaccines for children aged 5-11 years is expected to reopen against the 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. Additional information on weekly thresholds after the initial set of thresholds will be forthcoming.

The following summary table provides an estimated sequence of events based on bivalent Pfizer-BioNTech vaccines for children aged 5-11 years receiving an EUA by early to mid-October. Additional details regarding the vaccine ordering timeline and delivery of vaccine shipments will be updated when available.

Projected Timeline (All subject to change)	**Action/Event**	**Comments**
Pre-EUA		
Ongoing	Moderna bivalent vaccine ordering/delivery is ongoing against current thresholds for 18+	
9/20/22	Pfizer-BioNTech (pediatric 5-11) thresholds posted for planning (pro rata per jurisdiction)	Posted in Tiberius
9/21/22	All-Awardee call	
9/26/22	Pfizer-BioNTech (pediatric 5-11) pre-ordering begins	10:00 a.m. ET opening

Projected Timeline (All subject to change)	Action/Event	Comments
9/28/22	Special ad hoc all-awardee call with Pfizer-BioNTech and Moderna in attendance	
10/05/22	Pfizer-BioNTech (pediatric 5-11) pre-ordering Ends	Cutoff at 9:00 a.m. ET
Post-EUA		
Ongoing	Moderna bivalent vaccine ordering/delivery is ongoing against the established 18+ thresholds	
TBD (pending EUA)	CDC recommendations by decision memo	
TBD (pending EUA)	First deliveries of Pfizer-BioNTech (pediatric 5-11) vaccine arrive	
TBD (pending EUA, CDC recommendation)	Vaccine partner update calls	
TBD	Post-EUA Pfizer-BioNTech (pediatric 5-11) thresholds posted (pro rata per jurisdiction)	

UPDATED CONSIDERATIONS FOR JURISDICTIONS: PEDIATRIC GROUPS

To enhance readiness to launch the pediatric bivalent vaccine program and begin administering vaccine, jurisdictions should identify providers who will receive the bivalent doses. Also, jurisdictions will need to balance making primary series vaccine accessible to those who would like to receive it while avoiding distributing inventories across too many sites and seeking to minimize vaccine loss.

Jurisdictions and providers are **strongly encouraged to adopt strategies to minimize unnecessary wastage**, however, **they should not miss any opportunities to vaccinate every eligible person** who requests a vaccination, even if it means puncturing a multidose vial to administer vaccine without having enough people available to receive each dose in the vial.

Pediatric bivalent COVID-19 vaccines will be made available to jurisdictions, pharmacies, and federal entities through pro rata thresholds (based on the eligible population rather than census population). Jurisdictions should create a distribution plan in coordination with local health departments and other partners and determine which sites will receive vaccine product, incorporating the considerations listed below.

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

- Location and access to a range of populations (e.g., urban and rural, communities that may be disproportionately impacted by COVID-19) and ensuring that distribution to these groups is equitable to the extent possible.
- Ability to reach eligible children at highest risk for severe COVID-19.
- Ability to handle 100-dose product configurations, depending on whether the jurisdiction has plans in place for redistribution.
- Ability to administer both Pfizer-BioNTech and Moderna bivalent vaccines to meet anticipated community demand.
- Ability to efficiently vaccinate within 12 hours once a vial is opened. Sites should consider vial size and the expected demand when planning and scheduling individuals for vaccination, especially early in the program, to optimize supply.
- Ability to manage inventory to ensure availability of primary series doses, in addition to bivalent vaccine doses, in their local area when feasible.
- Overall readiness (e.g., staffing, training, scheduling capabilities).

Jurisdictions will be responsible for assuring primary vaccines remain available especially in populations where uptake of the primary series is lower, such as children. **It is anticipated that pediatric bivalent COVID-19 vaccines will be authorized only as a single booster dose in children who have completed a primary vaccination series, at a minimum interval after their last primary series dose or receipt of a prior booster dose.**

Currently, only a single booster dose of monovalent Pfizer-BioNTech COVID-19 vaccine is authorized and recommended for children aged 5-11 years who completed a primary series with the COVID-19 Pfizer-BioNTech vaccine. It is expected that heterologous (mix-and-match) bivalent vaccines will be authorized, meaning eligible children who completed a primary series of Pfizer-BioNTech vaccine would be able to receive a bivalent Moderna vaccine (or vice versa). It is also expected that eligible adolescents aged 12-17 years will have the option of receiving either Moderna or Pfizer-BioNTech bivalent vaccine.

In order to continue offering primary series vaccines in addition to bivalent vaccine for those who have already received their primary series vaccination, providers will need to keep multiple COVID-19 vaccine products in their inventory throughout the fall. CDC recommends providers offer simultaneous administration of all age-appropriate doses of vaccines for children, adolescents, and adults for whom no contraindications exist at the time of the healthcare visit.

As the demand for seasonal flu vaccines will also increase during this time, providers may have some concerns regarding vaccine storage space. To better maintain vaccine storage space, providers are encouraged to:

- Manage inventory to ensure availability of primary series doses, in addition to bivalent vaccines.
- Assess storage space to determine freezer and refrigerator capacity before placing orders for vaccine, taking into account anticipated flu vaccine inventory as appropriate.
- Check expiry dates on inventory and dispose of expired vaccine according to state and local regulations.
- Reduce vaccine ordering, reduce inventory, and place orders on an “as-needed” basis. In most instances, vaccine orders of existing COVID-19 vaccines can be delivered within 24-48 hours.
- Zero out old inventory in Vaccines.gov, and ensure the publicly posted amount reflects actual inventory on hand. This will help to reduce confusion and assist the public in identifying a location where they can receive a vaccine.

READINESS CHECKLIST

Main Theme	Key Activities for Readiness and Response
Supply and Ordering Readiness	❑ Determine which provider locations will receive initial supplies of each vaccine, balancing equitable access with vaccination capacity and consideration of initial demand. ❑ Finalize a list of providers and sequence of provider activation for the first week of vaccine deliveries. Jurisdictions will submit pre-orders for providers to facilitate delivery of orders. ❑ Review CDC and manufacturer materials regarding product configuration, shipping, storage, dosing, dosing intervals, and adverse event profiles as they become available. ❑ Optimize vaccine use by ordering supply to minimize unnecessary accumulation of inventory and wastage while also ensuring no vaccination opportunity is missed. ❑ Plan for internal redistribution (e.g., in a jurisdiction) to reduce wastage & improve access. ❑ Manage and accurately report on-hand product inventory to inform tracking near-expiry and redistribution.
Provider Readiness	❑ Ensure providers are enrolled to reach the key populations; identify 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 people who are at increased risk for developing severe outcomes.

	❑ Ensure providers or other on-location staff are equipped and trained to respond to possible severe allergic reactions, like anaphylaxis. ❑ Encourage providers to offer COVID-19, influenza, or other routine vaccines, as feasible, to additional eligible persons (e.g., family members, community members). ❑ Ensure providers are aware of resources to help support coadministration of COVID-19 vaccines and other vaccines, including influenza vaccines, during a visit. ❑ Reinforce how 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 enrollment in v-safe. ❑ Encourage providers who are not able to offer COVID-19 vaccination to refer their patients to nearby vaccination providers.
IT Systems, Reporting and Monitoring	❑ Ensure electronic systems, including immunization information systems (IISs), are prepared to report and track vaccine administration. ❑ Remember that the Special Project Provider 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. ❑ Once the vaccination program begins, continue to leverage Tiberius dashboards to monitor the program.
Comms	❑ Create a communication plan that outlines strategies, audiences, and products that will be used to promote COVID-19 vaccination of unvaccinated key populations and populations recommended for bivalent vaccination. ❑ Understand existing data, attitudes, and perceptions regarding COVID-19 vaccination (including co-administration with influenza vaccine) in terms of demand, provider types, and locations where vaccination would be preferred. Share these data with local jurisdictions and partners to help shape messages. ❑ Develop communications products for providers, pharmacies, and the public that align with federal messaging and ensure materials are culturally and linguistically appropriate. ❑ Leverage partnerships to help mobilize providers and promote COVID-19 bivalent vaccination messaging. ❑ Engage and educate partners and trusted messengers (e.g., healthcare professionals, community leaders, faith leaders and faith-based organizations) as soon as possible.