Planning for the Pediatric Bivalent COVID-19 Booster Rollout

September 29, 2022
On Today’s Call

- Illinois Department of Public Health
- Chicago Department of Public Health
- ICAAP/I-VAC: Dr. Christina Wells

Administration of bivalent boosters to children 5-11 years old cannot begin until after FDA EUA is issued AND a CDC recommendation is granted.

All information is subject to change.
What is a Bivalent COVID-19 Vaccine?

- **From Moderna:** Bivalent vaccines are designed to protect against two strains of a virus providing greater protection against variants compared to the original Moderna COVID-19 Vaccine.

- **From Pfizer:** The Omicron BA.4/BA.5-adapted bivalent vaccine contains mRNA encoding the wild-type spike protein of SARS-CoV-2 in the Original Pfizer-BioNTech COVID-19 Vaccine, and mRNA encoding the spike protein of the Omicron BA.4/BA.5 subvariants. Apart from the addition of the mRNA sequence of the BA.4/BA.5 spike protein, all other components of the vaccine remain unchanged.
Pediatric Bivalent COVID-19 Boosters

- 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.
  - ACIP meetings scheduled for: October 19-20

- Ages and products:
  - **Pfizer-BioNTech**: for children 5-11 years
  - **Moderna**: for children 6-17 years

UPDATED: September 20, 2022: 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
Anticipated Guidance

▶ Pediatric bivalent COVID-19 vaccines will be:
  ▶ A single booster dose in children who have completed a primary vaccination series at a minimum interval after their last COVID-19 dose.

▶ It is expected that heterologous (mix-and-match) bivalent vaccines will be authorized, e.g.:
  ▶ Children who completed a primary series of Pfizer-BioNTech vaccine would be able to receive a bivalent Moderna vaccine (or vice versa).
  ▶ Adolescents 12-17 years old will have the option of receiving either Moderna or Pfizer bivalent vaccine.
Anticipated Guidance

- Monovalent mRNA COVID-19 vaccines would NO LONGER be authorized for use as boosters in children 5 years and older.
- No changes to primary vaccine products.
- No changes to the schedule for 6 months to 4 years-old.
# STORAGE & HANDLING

## PFIZER-BIONTECH STORAGE & HANDLING INFORMATION

<table>
<thead>
<tr>
<th>AGE INDICATIONS</th>
<th>6 months through 4 years</th>
<th>5 years through 11 years</th>
<th>5 years through 11 years</th>
<th>12 years and older</th>
<th>12 years and older</th>
</tr>
</thead>
<tbody>
<tr>
<td>FORMULATION</td>
<td>Primary Series</td>
<td>Primary Series</td>
<td>Single Bivalent Booster Dose</td>
<td>Primary Series</td>
<td>Single Bivalent Booster Dose</td>
</tr>
<tr>
<td>VIAL CAP COLOR/ LABEL WITH COLOR BORDER</td>
<td>Maroon</td>
<td>Orange</td>
<td>Orange/Bivalent label</td>
<td>Gray</td>
<td>Gray</td>
</tr>
<tr>
<td>PREPARATION</td>
<td>Dilute Before Use</td>
<td>Dilute Before Use</td>
<td>Dilute Before Use</td>
<td>Do Not Dilute</td>
<td>Do Not Dilute</td>
</tr>
<tr>
<td>AMOUNT OF DILUENT NEEDED PER VIAL*</td>
<td>2.2 mL</td>
<td>1.3 mL</td>
<td>1.3 mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DOSE VOLUME/DOSE</td>
<td>0.2 mL/3 mcg</td>
<td>0.2 mL/10 mcg</td>
<td>0.2 mL/10 mcg</td>
<td>0.3 mL/30 mcg</td>
<td>0.3 mL/30 mcg</td>
</tr>
<tr>
<td>DOSES PER VIAL</td>
<td>10 primary (after dilution)</td>
<td>10 primary (after dilution)</td>
<td>10 booster (after dilution)</td>
<td>6 primary</td>
<td>6 booster</td>
</tr>
<tr>
<td>ULT FREEZER (-90°C TO -60°C)*</td>
<td>12 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FREEZER (-25°C TO -15°C)</td>
<td>DO NOT STORE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>REFRIGERATOR (2°C TO 8°C)</td>
<td>10 weeks</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ROOM TEMPERATURE (8°C TO 25°C) including any thaw time</td>
<td>12 hours prior to first puncture</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AFTER FIRST PUNCTURE (2°C TO 25°C)</td>
<td>Discard after 12 hours</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Diluent: Sterile 0.9% Sodium Chloride Injection, USP. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.

* Pending Authorization*
Storage & Handling Pfizer

The **ORANGE** caps and **ORANGE** vial label borders of both vaccines are **IDENTICAL**

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**Pfizer-BioNTech COVID-19 Vaccine**

*Primary Series Only*

**Pfizer-BioNTech COVID-19 Vaccine, Bivalent**

*(Original and Omicron BA.4/BA.5)*

*Booster Dose Only*

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**Multiple-Dose Vial Thaw Time**

- Refrigerator (2°C to 8°C): Up to 4 hours
- Room Temperature (up to 25°C): 30 minutes

- After dilution with 1.3 mL of 0.9% Sodium Chloride Injection, USP, the vial contains 10 doses of 0.2 mL (10 mcg)
- Prior to withdrawing a dose, check that the vial has not reached the 12-hour post-dilution expiration
- Withdraw 0.2 mL dose (10 mcg) of Orange Cap vaccine for administration to individuals 5 through 11 years of age
- Any vaccine remaining in vials (or syringes) should be discarded 12 hours after dilution

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*Pending Authorization*
## STORAGE & HANDLING
### MODERNA STORAGE & HANDLING INFORMATION

<table>
<thead>
<tr>
<th>AGE INDICATIONS AND FORMULATION</th>
<th>6 months through 5 years (Primary Series)</th>
<th>6 years through 11 years (Primary Series)*</th>
<th>12 years and older (Primary Series)**</th>
<th>6 years and older (Single Bivalent Booster Dose)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VIAL CAP COLOR</td>
<td>Dark Blue</td>
<td>Dark Blue</td>
<td>Red (5.5 mL)</td>
<td>Dark Blue</td>
</tr>
<tr>
<td>VIAL LABEL BORDERS COLOR</td>
<td>Magenta</td>
<td>Purple</td>
<td>Light Blue</td>
<td>Gray</td>
</tr>
<tr>
<td>PREPARATION</td>
<td>Do Not Dilute</td>
<td>Do Not Dilute</td>
<td>Do Not Dilute</td>
<td>Do Not Dilute</td>
</tr>
<tr>
<td>DOSE VOLUME/DOSE</td>
<td>0.25 mL/25 mcg</td>
<td>0.5 mL/50 mcg</td>
<td>0.5 mL/100 mcg primary</td>
<td></td>
</tr>
<tr>
<td>DOSES PER VIAL</td>
<td>10 primary doses</td>
<td>5 primary doses</td>
<td>11 max primary doses</td>
<td></td>
</tr>
</tbody>
</table>

### ULT FREEZER
(-90°C TO -60°C)

| FREEZER (-50°C TO -15°C)*       | DO NOT STORE                              | Until expiration                         | 30 days                                |
| REFRIGERATOR (2°C TO 8°C)       | 24 hours                                  | 24 hours                                 |                                       |

### ROOM TEMPERATURE (8°C TO 25°C) including any thaw time

**Pending Authorization**

- Regardless of storage condition, vaccines should not be used after the expiration date.
- After a vial is punctured 20 times it should be discarded even if the 12-hour time limit has not been met.
- Can be used as a dose in those who received a J & J primary dose.
- Although labels may state "booster doses only", the blue cap, purple label border presentation is only for use as a primary dose in ages 6-11
# Ordering Information

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Pfizer</th>
<th>Pfizer*</th>
<th>Moderna*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bivalent Booster 5-11</td>
<td>Bivalent Booster 12+</td>
<td>Bivalent Booster 6+</td>
</tr>
<tr>
<td># vials per tray</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td># doses per tray</td>
<td>100</td>
<td>60</td>
<td>50</td>
</tr>
<tr>
<td>Minimum order quantity</td>
<td>1 tray (100 doses)</td>
<td>5 trays (300 doses)</td>
<td>2 trays (100 doses)</td>
</tr>
<tr>
<td>Delivery time</td>
<td>~1 week</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Ancillary supplies will be provided for bivalent products, including a variety of 1-inch and 1.5-inch needles and syringes. *Opt-out is available for Pfizer 12+ bivalent and Moderna – NOT for 5-11 bivalent.

*Pending Authorization*
Ancillary Kits

- Bivalent Moderna COVID-19 vaccines for children aged 6-11 years, if authorized.
  - 2 ancillary kits per minimum dose order will be sent 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.
Ordering

IDPH

▷ Pre-ordering is open now in I-CARE for Pfizer COVID-19 Bivalent for ages 5-11 years.
▷ Ordering for Moderna COVID-19 bivalent for ages 6-17 years will occur post-EUA.
Ordering

▷ CDPH
▷ Reach out to COVID19vaccine@cityofchicago.org
**Pfizer**

**Pfizer-BioNTech**
- **Ages 6 months–4 years**
  - Dose/Injection Volume: 8.0 mL (10 µg/0.2 mL)
  - Primary Dose: Maroon Cap

**Pfizer-BioNTech**
- **5 year olds ONLY**
  - Dose/Injection Volume: 10 µg/0.2 mL
  - Primary/Booster Dose: Pfizer Orange Cap

**Pfizer-BioNTech**
- **Ages 6 years–11 years**
  - Dose/Injection Volume: 10 µg/0.2 mL
  - Primary Dose: Pfizer Orange Cap
  - Bivalent Booster: Pfizer Orange Cap or Moderna Dark Blue Cap (gray label)

**Pfizer-BioNTech**
- **Ages 12 years and older**
  - Dose/Injection Volume: 30 µg/0.3 mL
  - Primary Dose: Gray Cap
  - Bivalent Booster: Pfizer Gray Cap (gray label) or Moderna Dark Blue Cap (gray label)

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*Example: Pending Authorization*

See the Pfizer-BioNTech COVID-19 Vaccine Guidance for children who are transitioning from a younger to older age group during their vaccination window.

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* Complete the primary series with same product. If the vaccine product previously administered cannot be determined or is no longer available, any age-appropriate mRNA COVID-19 vaccine product may be administered at least 28 days after the first dose.

† Persons with a recent SARS-CoV-2 infection may consider delaying a primary series or booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic).

‡ Some studies in adolescents and adults have shown the small risk of myocarditis associated with mRNA COVID-19 vaccines might be reduced and peak antibody responses and vaccine effectiveness may be increased with an interval longer than 4 weeks. An 8-week interval may be optimal for people who are not moderately or severely immunocompromised and ages 6 months–64 years, especially for males ages 12–19 years. Source: CDC.

See the CDC’s Guidance for latest updates and information on who is considered moderately or severely immunocompromised.

ilinoisvaccinates.com
Example:
*Pending Authorization*

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[See the CDC’s Guidance for latest updates and information on who is considered moderately or severely immunocompromised.]

illinoisvaccinates.com
Modern

**Example:**

*Pending Authorization*

See the Moderna COVID-19 Vaccine Guidance for children who are transitioning from a younger to older age group during their vaccination window.

* Complete the primary series with same product. If the vaccine product previously administered cannot be determined or is no longer available, any age-appropriate mRNA COVID-19 vaccine product may be administered at least 28 days after the first dose.

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illinoisvaccinates.com
**Moderna** For Moderately to Severely Immunocompromised Populations

![Diagram of Moderna vaccination schedule for different age groups: 6 months to 4 years, 5 years old, 6 to 11 years, 12 years and older.]

*Example: Pending Authorization*

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[illinoisvaccinates.com]
Janssen and Novavax

Janssen (J&J)
Ages 18 years and older
- dose/injection volume: 5 ml
- Bivalent Boosters:
  - Pfizer Gray Cap (gray label)
  - Moderna Dark Blue Cap (gray label)

Novavax
Ages 12 years and older
- dose/injection volume: 55 mg/0.5 mL
- Bivalent Boosters:
  - Pfizer Gray Cap (gray label)
  - Moderna Dark Blue Cap (gray label)

Example: *Pending Authorization*

All charts are available at illinoisvaccinates.com/resources
Additional Information

Provider facilities that do not require minimum order quantities should contact their local health department or other typical sources for vaccine redistribution, such as the State Vaccine Reallocation Tool.

Providers are asked to report their inventory to Vaccines.gov as soon as possible – *include ages please!*
Reminders

➢ Some wastage is expected in order to vaccinate all eligible Illinoisians.

➢ Providers will NOT be penalized for wasting the remainder of a vial if they are only able to utilize a portion of the doses in the vial.
FAQs

What safety data do we have?

▷ Both Moderna and Pfizer have shared data on the safety of the BA.1 bivalent vaccine on over 1,400 adults.
  ▷ The bivalent vaccine that will be available in the US is the BA.5 bivalent vaccine, but the differences between the two (BA.1 and BA.5) is very small.
  ▷ According to Your Local Epidemiologist, "The difference is a few amino acids or equivalent to a few letter edits on a Word document. We aren’t changing the number of words in the paper (like dosage of RNA), or the content of the paper, or the platform (like Word to Excel). Because of the minimal change, we are confident that BA.1 bivalent safety data will accurately reflect BA.5 safety. The risk of myocarditis after COVID-19 infection (compared to vaccination) is 1.8 - 5.6 times higher among young males."
FAQs

Can patients mix and match products?

Currently: Yes.

For booster vaccination, age-appropriate mRNA vaccines are recommended. Any homologous or heterologous age-appropriate mRNA vaccine can be used if a booster dose is FDA-authorized for use in a specified population.

• Homologous booster dose: The same vaccine manufacturer used for the booster dose and the primary series.
• Heterologous booster dose (mix-and-match booster): A different vaccine manufacturer used for the booster dose and the primary series.

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html
FAQs

Can other vaccines be given with bivalent boosters?

▶ YES!

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.

There are additional considerations if administering an orthopoxvirus vaccine (see CDC guidance).

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html
Talking to Parents and Caregivers

Why do we need an updated booster?

For more protection from COVID-19. Each booster helps to give longer protection. The COVID-19 virus has changed since the vaccines first came out and we now have the Omicron strain. A bivalent vaccine will provide even more protection against current and future strains of the virus related to Omicron.

Why should my child get an updated booster?

Cases are probably going to increase this winter due to more time spent inside and fewer masking requirements. The virus is continuously changing and we have to change with it! Staying up to date with vaccines is the best way to avoid hospitalization, death, and other long term health conditions that we know COVID-19 can and does cause.
COVID-19 Vaccination Record Cards

If vaccination card is full:

- CDC recommends completing a second card and stapling the two cards together.
- Encourage the patient to photograph both cards in case the two become separated, if possible.
- Both cards should be presented when vaccination history is required for travel, employment, or other purposes.
- Encourage patients to download their vaccine records with VaxVerify.
Upcoming Trainings and Support

<table>
<thead>
<tr>
<th>ADVISOR OFFICE HOURS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tuesday</td>
</tr>
<tr>
<td>Friday</td>
</tr>
<tr>
<td>Thursday</td>
</tr>
<tr>
<td>Tuesday</td>
</tr>
</tbody>
</table>

- **I-VAC Office Hours**
  - Follow [this link](#) to join on Zoom
- **Learning Collaborative sessions, held bi-weekly**
  - **Pediatric sessions** begin Tuesday, October 11<sup>th</sup> 5:30pm to 6:30pm
  - **Adult sessions** begin Wednesday, October 19<sup>th</sup> 5:30pm to 6:30pm
- **Moderna**
  - Trainings [link](#)
  - Office hours and regional contacts [link](#)
- **Pfizer**
  - Trainings [link](#)
Additional Resources + Outreach Materials

- Standing orders
  - Moderna
  - Pfizer
- Illinois Vaccinates Against COVID-19 (I-VAC)
  - Bivalent social media images available
- Provider FAQs here
- Patient-Facing COVID-19 Vaccine FAQs
  - Pediatrics COVID-19 Vaccines – English, Spanish
  - Updated COVID-19 Boosters – English, Spanish
  - NEW Pediatric updated COVID-19 Boosters – English, Spanish

- AAP dosing guide for when a child has birthdays in between doses here
- Pfizer trainings here
- Fall bivalent boosters: Science update from YLE here
gain knowledge
A lot has changed in terms of eligibility and clinical guidance around COVID-19 vaccines. It is important now more than ever to ensure your facility and staff are up to date on COVID-19 information. Practice skills through activities.

connect with peers
While gaining skills related to COVID-19 vaccine administration and distribution. Learn strategies for overcoming vaccine hesitancy through culturally and linguistically appropriate methods.

get free CME/CE
The Illinois Chapter, American Academy of Pediatrics is accredited by the Illinois State Medical Society (ISMS) to provide continuing medical education for physicians. The Illinois Chapter, American Academy of Pediatrics designates each live training for a maximum of 1.00 AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity. Nurses and Nurse Practitioners can submit Certificate of Attendance to their accounting board to claim credit for participation in the live webinar.

Registration information coming soon
Contact Information

IDPH
▷ To enroll in I-CARE: dph.immunizations@illinois.gov
▷ For questions about vaccine orders: dph.vaccines@illinois.gov

CDPH
▷ Kevin Hansen: Kevin.Hansen@cityofchicago.org
▷ COVID19vaccine@cityofchicago.org
▷ Provider resources: https://www.chicagohan.org/covid-19-vaccine/provider

ICAAP/I-VAC
▷ Illinois Vaccinates Against COVID-19
▷ Stephanie Atella: satella@illinoisaap.com

▷ Facts@ilvaccinates.com

Pfizer
▷ Customer Service: Call 1-800-879-3477
▷ General Product Inquiries: Call 1-877-829-2619
▷ Pfizer Medical Information: Call 1-800-438-1985 or Visit PfizerMedicalInformation.com
▷ Controlant Customer Support: 1-701-540-4039
▷ Pfizer US Shipment Support: Call 1-800-666-7248

Moderna
▷ Customer Service: Call 1-866-MODERNA (1-866-663-3762) or Email ModernaPV@moderntx.com
▷ Chatbot here
Thank You

Stay tuned.

It is anticipated that at least one bivalent vaccine for children aged 6 months to 4 years may be authorized later in the fall. Keep this and storage space in mind when developing your overall fall vaccine plans.