Pediatric Bivalent COVID-19 Boosters

October 12, 2022
On Today’s Call

- Illinois Department of Public Health
- Chicago Department of Public Health
- ICAAP: Susan Sirota, MD, FAAP
FDA Authorized as of 10.12.22

Coronavirus (COVID-19) Update: FDA Authorizes Moderna and Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose in Younger Age Groups

For Immediate Release: October 12, 2022

Today, the U.S. Food and Drug Administration amended the emergency use authorizations (EUAs) of the Moderna COVID-19 Vaccine, Bivalent and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent to authorize their use as a single booster dose in younger age groups. The Moderna COVID-19 Vaccine, Bivalent is authorized for administration at least two months following completion of primary or booster vaccination in children down to six years of age. The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is authorized for administration at least two months following completion of primary or booster vaccination in children down to five years of age.

These bivalent COVID-19 vaccines include an mRNA component of the original strain to provide increased protection against COVID-19 strains and are mRNA.

AND

Signed off by the CDC as of 10.12.22

CDC Expands Updated COVID-19 Vaccines to Include Children Ages 5 Through 11

For Immediate Release: Wednesday, October 12, 2022
Contact: Media Relations
(404) 639-3286

Today, CDC’s Director Rochelle P. Walensky, M.D., M.P.H., signed a decision memo expanding the use of updated (bivalent) COVID-19 vaccines to children ages 5 through 11 years. This follows the Food and Drug Administration’s (FDA) authorization of updated COVID-19 vaccines from Pfizer-BioNTech for children ages 5 through 11 years, and from Moderna for children and adolescents ages 6 through 17 years.

Updated COVID-19 vaccines add Omicron BA.4 and BA.5 spike protein components to the current vaccine composition, helping to restore protection that has waned since previous vaccination and targeting recent Omicron variants that are more transmissible and immune-avoiding.

FDA’s authorization of updated (bivalent) COVID-19 vaccines for this younger age group, and CDC’s recommendation for use, are critical next steps forward in our country’s vaccination program—a program that has helped provide increased protection against severe COVID-19 disease and death.

You may now start administering bivalent boosters to children 5 years and older, per the EUA guidance.
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

- Ages and products:
  - Pfizer-BioNTech: for children 5-11 years
    - [FDA fact sheet for health care providers administering Pfizer-BioNTech bivalent boosters](#)
  - Moderna: for children 6-17 years
    - [FDA fact sheet for health care providers administering Moderna bivalent boosters](#)

Monovalent mRNA COVID-19 vaccines are NO LONGER authorized for use as boosters in children 5 years and older.
Guidance

▷ A single booster dose in children who have completed a primary vaccination series two months after their last COVID-19 dose.

▷ Heterologous (mix-and-match) bivalent vaccines is authorized.

▷ No changes to primary vaccine products. Bivalent products are not to be used as primary series vaccines.

▷ 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></td>
<td></td>
<td></td>
<td>12 months</td>
<td></td>
</tr>
<tr>
<td>FREEZER (-25°C TO -15°C)</td>
<td></td>
<td></td>
<td></td>
<td>DO NOT STORE</td>
<td></td>
</tr>
<tr>
<td>REFRIGERATOR (2°C TO 8°C)</td>
<td></td>
<td></td>
<td></td>
<td>10 weeks</td>
<td></td>
</tr>
<tr>
<td>ROOM TEMPERATURE (8°C TO 25°C) including any thaw time</td>
<td></td>
<td></td>
<td></td>
<td>12 hours prior to first puncture</td>
<td></td>
</tr>
<tr>
<td>AFTER FIRST PUNCTURE (2°C TO 25°C)</td>
<td></td>
<td></td>
<td></td>
<td>Discard after 12 hours</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.

* Regardless of storage condition, vaccines should not be used after 12 months from the date of manufacture printed on the vial and cartons.
## 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 BORDER 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>
<tr>
<td>ULT FREEZER (-90°C TO -60°C)</td>
<td>DO NOT STORE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FREEZER (-50°C TO -15°C)*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>REFRIGERATOR (2°C TO 8°C)</td>
<td></td>
<td></td>
<td>30 days</td>
<td></td>
</tr>
<tr>
<td>ROOM TEMPERATURE (8°C TO 25°C)</td>
<td></td>
<td></td>
<td>24 hours</td>
<td></td>
</tr>
<tr>
<td>INCLUDING ANY THAW TIME</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AFTER FIRST PUNCTURE (2°C TO 25°C)*</td>
<td></td>
<td></td>
<td>Discard after 12 hours</td>
<td></td>
</tr>
</tbody>
</table>
## 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.
Ancillary Kits

- Bivalent Moderna COVID-19 vaccines will come with 2 ancillary kits per minimum dose order will be sent to accommodate double the number of doses provided in each vial.
- Specify pediatric intent within vaccine orders to receive the appropriate ancillary kit.
- An ancillary opt-out continues to be available for all non-diluent kits.

Chicago sites: To opt out of ancillary supply kits, please email COVID19vaccine@cityofchicago.org
Ordering Pediatric Bivalent Vaccines

▷ CDPH through redcap surveys

▷ IDPH – through I-CARE
Pfizer

Pfizer-BioNTech
Ages 6 months–4 years
* 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.

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

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

For ages 6 months to 11 years old:
- Primary Dose: Maroon Cap
- Booster Dose: Pfizer Orange Cap

For ages 12 years and older:
- Primary Dose: Gray Cap
- Booster Dose: Pfizer Orange Cap or Moderna Dark Blue Cap (gray label)

*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 to 4 years, especially for males ages 12-39 years. Source: CDC

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

Modern
Ages 6 months–4 years
dose/injection volume (Do NOT dilute before use)
Primary Dose:
Blue Cap (magenta label)

Modern
5 year olds ONLY
dose/injection volume (Do NOT dilute before use)
Primary Dose:
Blue Cap (magenta label)
Bivalent Booster:
Pfizer Orange Cap

Modern
Ages 6 years–11 years
dose/injection volume (Do NOT dilute before use)
Primary Dose:
Blue Cap (purple label)
Bivalent Booster:
Moderna Dark Blue Cap (gray label) or Pfizer Orange Cap

Modern
Ages 12 years and older
dose/injection volume (Do NOT dilute before use)
Primary Dose:
Red Cap (blue label)
Bivalent Booster:
Moderna Dark Blue Cap (gray label) or Pfizer Gray Cap (gray label)

In at least 2 months

In 4-8 weeks

* Complete the primary series with the 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–4 years, especially for males ages 12–19 years. Source: CDC.

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

See the CDC’s Guidance for latest updates and information on who is considered moderately or severely immunocompromised.
**Moderna** For Moderately to Severely Immunocompromised Populations

*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.*

1. 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).

2. 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 12–39 years. Source: CDC.

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

iinoisvaccinates.com
Janssen and Novavax

Janssen (J&J)
Ages 18 years and older
dose/injection volume
5x10^9 and particles 1.5 mL
Bivalent Boosters:
Pfizer Gray Cap (gray label) or Moderna Dark Blue Cap (gray label)

All updated charts are available at illinoisvaccinates.com/resources

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

Can patients mix and match products?

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
### Vaccine Coverage in 6 months to 4 years

As of 9.21.22, many were not due for dose 3 until the following week

<table>
<thead>
<tr>
<th></th>
<th>Pediatric Partners</th>
<th>PediaTrust</th>
</tr>
</thead>
<tbody>
<tr>
<td>At least one dose of either vaccine</td>
<td>42.0%</td>
<td>28.7%</td>
</tr>
<tr>
<td>At least two doses of Pfizer vaccine</td>
<td>29.0%</td>
<td>17.3%</td>
</tr>
<tr>
<td>Completed series</td>
<td>8.8%</td>
<td>7.2%</td>
</tr>
</tbody>
</table>

**Illinois**

<table>
<thead>
<tr>
<th>As of 9.18.22</th>
<th>First Dose</th>
<th>Second Dose</th>
<th>Third Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>9%</td>
<td>6%</td>
<td>1%</td>
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</tbody>
</table>

**Chicago**

<table>
<thead>
<tr>
<th>As of 10.6.22</th>
<th>First Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>13.6%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Completed Primary</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6.2%</td>
</tr>
</tbody>
</table>
Strategies for Increasing Uptake

simplify scheduling

▷ Alert patients when vaccines are coming
▷ Self-scheduling through patient portal
▷ Automatically schedule return visits
▷ Site options - mass vaccination clinics, drive-thru vaccination, sites at local high school, empty store fronts, etc.
Strategies for Increasing Uptake

**Streamline Operations**

- Pre-made vaccine card labels
- Only carry one vaccine manufacturer
- At mass vaccination clinics – use hot-spots to enter EHR information in real time
- Make sure you are getting reimbursed!
Strategies for Increasing Uptake

Create a culture of vaccine confidence

▷ Staff townhalls so everyone stays up-to-date
▷ Empower vaccine champions – they don’t have to be a clinician!
▷ Everyone in the office (the nurses, front desk staff, schedulers, MAs and all the doctors) understands the message
Strategies for Increasing Uptake

celebrate vaccination

▷ Show off COVID-19 vaccine stickers (on clothing, laptops, any visible place patients and families can see them)
▷ Marketing materials in waiting rooms and on social media
▷ Offer COVID-19 vaccination at every visit
▷ For hesitant people – treat it as an ongoing conversation
As winter approaches, the shortage of pediatric hospital beds is cause for alarm

It is October, and the system is already at risk of getting overwhelmed — not just in Illinois but throughout the country. Pediatricians throughout the U.S. confirm this situation: There are more children who need beds in the hospital than there are pediatric beds.
JOIN US IN-PERSON!

COVID-19 VACCINE BOOTCAMP

Thursday, Nov 3rd
9am - 2pm
Malcolm X College

- Gain up-to-date knowledge
- Connect with peers
- Practice real-world skills

Register at illinoisvaccinates.com or scan the QR code
Upcoming Trainings and Support

ADRVIOR OFFICE HOURS

<table>
<thead>
<tr>
<th>Day</th>
<th>Date</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Friday</td>
<td>October 14</td>
<td>12 pm–1 pm</td>
</tr>
<tr>
<td>Thursday</td>
<td>October 20</td>
<td>12 pm–1 pm</td>
</tr>
<tr>
<td>Tuesday</td>
<td>October 25</td>
<td>12 pm–1 pm</td>
</tr>
</tbody>
</table>

▷ I-VAC Office Hours
▷ Follow this link to join on Zoom

▷ Learning Collaborative sessions, held bi-weekly

Pediatric sessions Tuesday, October 25th at 5:30pm to 6:30pm &

Adult sessions Wednesday, November 2nd at 5:30pm to 6:30pm
Upcoming ICAAP Webinars

With Sue Hong, MD (Lurie)
Marielle Fricchione, MD, FAAP (Rush)
Heather Reid (IDPH)
Stephanie Gretsch, MPH (CDPH)

With Rupali Limaye, PhD, MPH, MA - Deputy Director of the International Vaccine Access Center at Johns Hopkins
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](#)
- Moderna
  - Trainings [link](#)
  - Office hours and regional contacts [link](#)
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

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 PfizerMedicallInformation.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@modernatx.com
▶ Chatbot here
Thank You

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.