Bivalent COVID-19 Boosters for Children 6 Months and Older

December 5, 2022
On Today’s Call

▶ Illinois Department of Public Health
▶ Chicago Department of Public Health

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

All information is subject to change.
Current Eligibility

▷ 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](#)

▷ 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 for 5+.

Monovalent mRNA COVID-19 vaccines are NOT authorized for use as boosters in children 5 years and older.
ACIP recommend 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+ and from Moderna for people aged 18+.

CDC updates Fall Vaccination Operational Planning Guide to include information on Bivalent COVID-19 Vaccines for Children Aged 6 Months Through 4 or 5 Years.

Pre-ordering begins.

FDA authorized bivalent formulations of the mRNA vaccines for use as a single booster dose at least two months following the last primary series dose or booster.

FDA expanded the EUAs of bivalent COVID-19 vaccines to authorize their use as a single booster dose in younger age groups.

CDC issues recommendation for the use of bivalent COVID-19 boosters among individuals aged 5+.

Anticipated authorization of Bivalent COVID-19 Vaccines for Children Aged 6 Months Through 4 or 5 Years expected.
Anticipated Eligibility - Pfizer

A single dose for children who have received two doses of a monovalent COVID-19 vaccine.

- Pfizer-BioNTech vaccine for children aged 6 months through 4 years.
- A third dose of bivalent vaccine can be used to complete a child’s primary series in this age group.
- Children who received three doses of monovalent Pfizer-BioNTech COVID-19 vaccine will not be authorized to receive a booster dose of bivalent COVID-19 vaccine at this time.

- CPT Codes: NDC 59267-0609-02; CVX 302
Anticipated Eligibility - Moderna

A single booster dose for children who have received two doses of a monovalent COVID-19 vaccine.

- Moderna vaccine for children aged 6 months through 5 years.
- Children will need to complete two doses of monovalent Moderna COVID-19 vaccine before receiving a bivalent booster.
- Note: Children 5 years of age and older are currently authorized to receive a Pfizer BioNTech bivalent booster.
- CPT Codes: NDC 80777-0283-99, CVX 230
The minimum interval between the last COVID-19 and a bivalent booster is expected to be two months, as with other ages groups.

Heterologous (mix-and-match) bivalent vaccines will/will not be authorized.

Chart will be updated by CDC here.
# 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>12 years and older</th>
<th>6 months through 4 years</th>
<th>5 years through 11 years</th>
<th>12 years and older</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Formulation</strong></td>
<td>Primary Series</td>
<td>Primary Series</td>
<td>Primary Series</td>
<td>Single Bivalent Primary Dose</td>
<td>Single Bivalent Booster Dose</td>
<td>Single Bivalent Booster Dose</td>
</tr>
<tr>
<td><strong>Vial Cap Color/Label With Color Border</strong></td>
<td>Maroon</td>
<td>Orange</td>
<td>Gray</td>
<td>Maroon</td>
<td>Orange/ Bivalent label</td>
<td>Gray</td>
</tr>
<tr>
<td><strong>Preparation</strong></td>
<td>Dilute Before Use</td>
<td>Dilute Before Use</td>
<td>Do Not Dilute</td>
<td>Dilute Before Use</td>
<td>Dilute Before Use</td>
<td>Do Not Dilute</td>
</tr>
<tr>
<td><strong>Amount of Diluent Needed Per Vial</strong></td>
<td>2.2 mL</td>
<td>1.3 mL</td>
<td>Do Not Dilute</td>
<td>2.2 mL</td>
<td>1.3 mL</td>
<td>Do Not Dilute</td>
</tr>
<tr>
<td><strong>Dose Volume/Dose</strong></td>
<td>0.2 mL/3 mcg</td>
<td>0.2 mL/10 mcg</td>
<td>0.3 mL/30 mcg</td>
<td>0.2 mL/3 mcg</td>
<td>0.2 mL/10 mcg</td>
<td>0.3 mL/30 mcg</td>
</tr>
<tr>
<td><strong>Doses Per Dose</strong></td>
<td>10 primary (after dilution)</td>
<td>10 primary (after dilution)</td>
<td>6 primary</td>
<td>10 primary (after dilution)</td>
<td>10 booster (after dilution)</td>
<td>6 booster or 1 booster</td>
</tr>
<tr>
<td><strong>Ult Freezer (-90°C to -60°C)</strong></td>
<td>12 months</td>
<td>12 months</td>
<td>12 months</td>
<td>12 months</td>
<td>12 months</td>
<td>12 months</td>
</tr>
<tr>
<td><strong>Freezer (-25°C to -15°C)</strong></td>
<td>DO NOT STORE</td>
<td>DO NOT STORE</td>
<td>DO NOT STORE</td>
<td>DO NOT STORE</td>
<td>DO NOT STORE</td>
<td>DO NOT STORE</td>
</tr>
<tr>
<td><strong>Refrigerator (2°C to 8°C)</strong></td>
<td>10 weeks</td>
<td>10 weeks</td>
<td>10 weeks</td>
<td>10 weeks</td>
<td>10 weeks</td>
<td>10 weeks</td>
</tr>
<tr>
<td><strong>Room Temperature (8°C to 23°C) Including Any Thaw Time</strong></td>
<td>12 hours prior to first puncture</td>
<td>12 hours prior to first puncture</td>
<td>12 hours prior to first puncture</td>
<td>12 hours prior to first puncture</td>
<td>12 hours prior to first puncture</td>
<td>12 hours prior to first puncture</td>
</tr>
<tr>
<td><strong>After First Puncture (2°C to 25°C)</strong></td>
<td>Discard after 12 hours</td>
<td>Discard after 12 hours</td>
<td>Discard after 12 hours</td>
<td>Discard after 12 hours</td>
<td>Discard after 12 hours</td>
<td>Discard after 12 hours</td>
</tr>
</tbody>
</table>

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* 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.
<table>
<thead>
<tr>
<th>Age Indications and Formulation</th>
<th>Primary</th>
<th>Booster</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>6 months through 5 years (Primary Series)</td>
<td>6 months through 5 years (Primary Series)</td>
</tr>
<tr>
<td><strong>Vial Cap Color</strong></td>
<td>Dark Blue</td>
<td>Dark Blue</td>
</tr>
<tr>
<td><strong>Vial Label Border Color</strong></td>
<td>Magenta</td>
<td>Purple</td>
</tr>
<tr>
<td><strong>Preparation</strong></td>
<td>Do Not Dilute</td>
<td>Do Not Dilute</td>
</tr>
<tr>
<td><strong>Dose Volume/Doze</strong></td>
<td>0.25 mL/25 mcg</td>
<td>0.5 mL/50 mcg</td>
</tr>
<tr>
<td><strong>Doses per Vial</strong></td>
<td>10 primary doses</td>
<td>5 primary doses</td>
</tr>
<tr>
<td><strong>Ult Freezer (-90°C to -60°C)</strong></td>
<td>DO NOT STORE</td>
<td>DO NOT STORE</td>
</tr>
<tr>
<td><strong>Freezer (-50°C to -15°C)</strong></td>
<td>Until expiration</td>
<td>Until expiration</td>
</tr>
<tr>
<td><strong>Refrigerator (2°C to 8°C)</strong></td>
<td>30 days</td>
<td>30 days</td>
</tr>
<tr>
<td><strong>Room Temperature (8°C to 25°C)</strong> including any thawing time</td>
<td>24 hours</td>
<td>24 hours</td>
</tr>
<tr>
<td><strong>After First Puncture (2°C to 25°C)</strong></td>
<td>Discard after 12 hours</td>
<td>Discard after 8 hours</td>
</tr>
</tbody>
</table>

* 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.
* 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.

subject to change
# Ordering Information

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Pfizer</th>
<th>Pfizer*</th>
<th>Pfizer*</th>
<th>Moderna*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bivalent vaccines 6 months to 11 years</strong></td>
<td>Bivalent Booster 12+</td>
<td>Bivalent Booster 12+ Single Dose Vials</td>
<td>Bivalent Booster 6 months to 4 years</td>
<td></td>
</tr>
<tr>
<td># vials per tray</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td># doses per tray</td>
<td>100</td>
<td>60</td>
<td>-</td>
<td>20</td>
</tr>
<tr>
<td>Minimum order quantity</td>
<td>1 tray (100 doses)</td>
<td>3 trays (180 doses for multiple dose vials)</td>
<td>50 doses</td>
<td>5 trays (100 doses)</td>
</tr>
<tr>
<td>Delivery time</td>
<td>~1 week</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- New single dose vials for Pfizer 12+ bivalent
- New minimum order quantity for Pfizer 12+
- Ancillary kits will still come in quantities of 300

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 pediatric products that do not require diluent.
PFIZER-BIONTECH COVID-19 VACCINATION SCHEDULE AND DOSING
UPDATE EXAMPLE

**Pfizer-BioNTech**
Ages 6 months–4 years
dose/injection volume (dilute before use)
Primary Dose:
Pfizer Mannan Cap
Bivalent Booster:
Pfizer Mannan Cap

In 3–8 weeks
PRIMARY
DOSE 1
3 μg/0.2 mL

In 3–8 weeks
PRIMARY
DOSE 2
3 μg/0.2 mL

In at least 8 weeks
Trip DOSE 3

Pfizer Monovalent: 3 g/0.2 mL
Pfizer Bivalent: 3 g/0.2 mL

**Pfizer-BioNTech**
5 year olds ONLY
dose/injection volume (dilute before use)
Primary Dose:
Pfizer Orange Cap
Bivalent Booster Options:
Pfizer Orange Cap
Moderna Dark Pink Cap (yellow label)

In 3–8 weeks
PRIMARY
DOSE 1
10 μg/0.2 mL

In at least 2 months
PRIMARY
DOSE 2
10 μg/0.2 mL

BOOSTER
BIVALENT

Pfizer: 10 μg/0.2 mL,
Moderna: 10 μg/0.2 mL

See the Pfizer-BioNTech 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.

† 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 increase 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.

Funding for this project was made possible by the Office of Disease Control through the Illinois Department of Public Health.

illinoisvaccinates.com
MODERNA COVID-19 VACCINATION SCHEDULE AND DOSING

UPDATED EXAMPLE

**Modern**
- **Ages 6 months—4 years**
  - Dose/Injection volume: 10 µg/0.5 mL
  - Primary Dose: Blue Cap (magenta label)
  - Bivalent Booster Options: Modern Dark Pink Cap (yellow label)

**Modern**
- **5 year olds ONLY**
  - Dose/Injection volume: 10 µg/0.5 mL
  - Primary Dose: Blue Cap (magenta label)
  - Bivalent Booster Options: Pfizer Orange Cap

**Modern**
- **Ages 6 years—11 years**
  - Dose/Injection volume: 10 µg/0.5 mL
  - Primary Dose: Blue Cap (purple label)
  - Bivalent Booster Options: Modern Dark Blue Cap (gray label)

**Modern**
- **Ages 12 years and older**
  - Dose/Injection volume: 30 µg/0.5 mL
  - Primary Dose: Red Cap (olive label)
  - Bivalent Booster Options: Modern Dark Blue Cap (gray label)

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**See the Pfizer-BioNTech 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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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
**HOLIDAY SHIPPING HOURS**

No vaccine will be delivered between December 22, 2022 and January 3, 2023.

**DECEMBER 2022**

- To ensure delivery in December, please submit vaccine orders by December 9, 2022.
- Limited deliveries will occur between December 15 and December 21, 2022, for vaccines ordered before the ordering deadline.

**JANUARY 2023**

- No vaccine will be delivered on January 2 or January 3, 2023.
- Post-holiday deliveries will resume on Wednesday, January 4, 2023.
- No vaccine will be delivered on January 16, 2022.

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**Ordering**

- Pediatric Bivalent Vaccines through I-CARE after pre-ordering
Pfizer Bivalent Vaccine in Single Dose Vials

- Bivalent booster (grey cap) for ages 12+
- New packaging, **not** new product
  - Box contains 10 vials per carton, each containing a single dose
  - Each dose is 0.3 mL, and no dilution is required
  - Same storage as all other Pfizer grey cap products
  - Ancillary kits not provided
  - Low-dead-volume syringes not required
- Limited access: review usage and storage – if interested in single dose vials, complete this [survey](#) by 12/7.
  - Minimum order: 50 vials, maximum order: 150 vials
  - Other opportunities to order may be available in the new year

*Wastage of multi-dose vials will still not be penalized*
HOLIDAY SHIPPING HOURS

Vaccine shipping will pause for the holidays starting in mid-December 2022.

ORDERS BEFORE DECEMBER 9, 2022

• Orders approved by Friday, December 9th will ship before the holiday pause.
• Any orders that are submitted without updated/correct inventories, incomplete temperature logs, or other errors may not be able to be approved and may delay shipments.

ORDERS AFTER DECEMBER 9, 2022

• Orders submitted after December 9th will still be processed and may ship before the holiday shipping pause.
• Orders that do not ship will be sent starting on January 3rd, 2023.

Ordering

- Pediatric Bivalent Vaccines through recap survey after pre-ordering
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.
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

Will patients be able to mix and match products?

▸ To be determined.

▸ Fall planning guide: Not expected in the newly authorized 6 months – 4 years age group.
FAQs

Can I vaccinate someone with a mild illness?

Absolutely, yes.

Per the 11.7.22 surge webinar with Dr. Barnes and Dr. Tan
FAQs

Can other vaccines be given with bivalent boosters?

▷ YES! This is not expected to change, as it is authorized for other age groups.
FAQs

**Will bivalent vaccines replace monovalent vaccines (primary series)?**

This may happen in the future. Until then:

- Continue getting all age groups vaccinated with the current primary series products, especially young pediatric age groups and groups at highest risk of poor outcomes.
Vaccine Coverage in 6 months to 4 years

- As of November 6th, 10.4% of Illinoisans aged 0-4 years have received at least one dose, 8.0% received 2 doses

National data:

Number and Proportion of US Infants and Children Ages 6 Months - 4 Years Receiving Initial Dose of COVID-19 Vaccine

- Cumulative
- Weekly

Upcoming Trainings and Support

I-VAC Office Hours
Follow [this link](#) to join on Zoom
Upcoming ICAAP Trainings

▷ Illinois Vaccinates Against COVID-19 (I-VAC) Vaccine Bootcamp (virtual)
  • December 16th, 8:00am – 12:15pm, CME available
  • Register here

▷ Vaccinations – Back to Basics with Dr. Nadia Qureshi
  • Register here
  • December 20th, 12:00 – 1:00pm, CME available

▷ Illinois Vaccinates Against COVID-19 (I-VAC) Vaccine Bootcamp (in person)
  • U of I Hotel and Conference Center (1900 S 1st St, Champaign, IL 61820)
  • Target Audience: Physicians, PAs, Advanced Practice Nurses, RNs, Pharmacists, MAs, Vaccine Administrators. Register here
  • January 20th, 8:30am – 2pm, CME available
Additional Resources

- **Age transitions chart from CDC**
- **Standing orders**
  - COVID-19 Moderna vaccine - 6 months through 5 years of age (dark blue vial cap with magenta [pink] bordered label)
  - COVID-19 Moderna vaccine - 6 years through 11 years of age (dark blue vial cap with purple bordered label)
  - COVID-19 Moderna vaccine - adults (12 years of age and older)
  - COVID-19 Novavax vaccine - adults (12 years of age and older)
  - COVID-19 Pfizer-BioNTech - 6 months through 4 years of age (maroon vial cap)
  - COVID-19 Pfizer-BioNTech - 5 through 11 years of age (orange cap)
  - COVID-19 Pfizer-BioNTech - 12 years and older (gray cap)
- **CDC Fall Planning Guide**
- **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](#)**
- **Pediatric updated COVID-19 Boosters – [English, Spanish](#)**
- **AAP dosing guide for when a child has birthdays in between doses** here
- **Pfizer trainings** here
- **Moderna**
  - Trainings [link](#)
  - Training for new products available after EUA
  - 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
- 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@modernatx.com
- Chatbot here
Thank You