Planning for the Bivalent COVID-19 Vaccine Rollout

Part Two – September 9, 2022 – starting at 12:05pm
On Today’s Call

▶ Illinois Department of Public Health: Karyn Lyons

▶ Chicago Department of Public Health: Maribel Chavez-Torres and Kevin Hansen

▶ ICAAP: Rachel Caskey, MD, MPP and Stephanie Atella
Details & Eligibility

▷ Administered as single dose booster to people who previously completed a primary COVID-19 vaccination series
▷ Number of previous boosters received **does not matter**
▷ Ages
  ▷ 12 years+ (Pfizer)
  ▷ 18 years+ (Moderna)
  ▷ Expected that at least one bivalent vaccine for children ages 11 years and younger may be authorized within a short time following the authorization(s) for older age groups
Details & Eligibility

- Monovalent mRNA CVOID-19 vaccines are NO LONGER authorized for use as boosters in people ages 12 years and older.
- No changes have been made to primary vaccines products.
- No changes have been made to the schedule for 6 months to 11-year-olds.
  - Those 5 years to 11 years can still be given the original (or monovalent) Pfizer vaccines as a booster.
## Storage & Handling Pfizer

<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>12 years and older</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formulation</td>
<td>Primary Series</td>
<td>Primary Series and 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>Gray</td>
<td>Gray</td>
</tr>
<tr>
<td>Preparation</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>Do Not Dilute</td>
<td>Do Not Dilute</td>
</tr>
<tr>
<td>Dose Volume/Dose</td>
<td>0.2 mL/3 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/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>
</tr>
<tr>
<td>Freezer (-25°C to -15°C)</td>
<td>DO NOT STORE</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>
</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>
</tr>
<tr>
<td>After First Puncture (2°C to 25°C)</td>
<td>Discard after 12 hours</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

*b* 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

<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>18 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>0.5 mL/50 mcg</td>
</tr>
<tr>
<td>Doses per Vial</td>
<td>10 primary</td>
<td>5 primary</td>
<td>11 max primary</td>
<td>5 booster</td>
</tr>
</tbody>
</table>

#### ULT Freezer (-90°C to -60°C)
- **DO NOT STORE**

#### Freezer (-50°C to -15°C) a
- Until Expiration

#### Refrigerator (2°C to 8°C)
- 30 Days

#### Room Temperature (8°C to 25°C) including any thaw time
- 24 hours

#### After First Puncture (2°C to 25°C) b
- Discard after 12 hours

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*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 suitable for use as a primary dose in ages 6-11.
Factsheets/VISs

Moderna
▶ FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)
▶ VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS

Pfizer
▶ FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)
▶ VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS
Bivalent Packing

STORE FROZEN between -50° to -15°C (-58° to 5°F).
Protect from light.
No preservative. After first use, hold at 2° to 25°C (36° to 77°F).
Discard after 12 hours.
Record date/time of first use:

Scan for expiry date,
FDA-authorized Fact Sheet and dose volume

Modern COVID-19 Vaccine, Bivalent
Original and Omicron BA.4/BA.5
Suspension for Intramuscular Injection
For use under Emergency Use Authorization

BOOSTER DOES ONLY
Multi-Dose Vial
Booster dose: 0.5 mL or 0.25 mL based on age

Pfizer-BioNTech COVID-19 Vaccine, Bivalent
Original and Omicron BA.4/BA.5
DO NOT DILUTE Age 12 y & older
Vial contains 6 doses of 0.3 mL
For intramuscular use. Contains no preservative.
For use under Emergency Use Authorization.
After first use store at 2 to 25°C (35 to 77°F)
and discard after 12 hours.
First use date and time:
# Ordering Information

<table>
<thead>
<tr>
<th></th>
<th>Pfizer</th>
<th>Moderna</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Formulation</strong></td>
<td>Bivalent Booster</td>
<td>Bivalent Booster</td>
</tr>
<tr>
<td># vials per tray</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td># doses per tray</td>
<td>60</td>
<td>50</td>
</tr>
<tr>
<td>Minimum order quantity</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>
</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.
Orders

Chicago Locations (CDPH) Chicago COVID-19 vaccine providers can request bivalent booster doses on the routine vaccine ordering survey [here](#).
Orders

▶ Non-Chicago Locations (IDPH) via I-CARE.
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!*
Reminder

▷ 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.
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.
FAQs

Is the bivalent booster available to uninsured patients free of charge?

Yes. The vaccine itself still cannot be charged for. While the HRSA (federal) uninsured program has come to an end, the Illinois Department of Healthcare and Family Services (HFS) (state) has continued funding and more information about vaccinating the insured and reimbursement for administration and vaccine counseling is available here.

Related: Getting Paid for COVID-19 vaccines article from the AAP
Questions

- Related to storage & handling
- Ordering

NEXT SECTION IS ON CLINICAL GUIDANCE
FAQs

Do patients have the option to decide which booster dose they may receive (original vs updated)?

No. Monovalent mRNA COVID-19 vaccines are NO LONGER authorized for use as boosters in people ages 12 years and older.
FAQs

Most commonly reported symptoms?
They are similar to the monovalent COVID-19 vaccines:

- Muscle pain
- Chills
- Joint pain
- Fever
- Headache
- Pain, redness and swelling at the injection site
- Fatigue
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?

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
Other 9.2.22 Updates

History of MIS-C or MIS-A

- The benefits outweigh a theoretical risk of a MIS-like illness for people who meet all the following criteria:
  1) Clinical recovery has been achieved, including return to normal cardiac function;
  2) It has been ≥90 days since their diagnosis of MIS-C;

Experts view clinical recovery, including return to baseline cardiac function, as an important factor when considering COVID-19 vaccination. Additional factors, such as the risk of severe COVID-19 due to age or certain medical conditions, may also be considered.

- Initiation of COVID-19 vaccination in people with a history of MIS-C/A should take into consideration current or planned immunomodulatory therapies for treatment of MIS-C/A (see Considerations for timing of COVID-19 vaccination in relation to immunosuppressive therapies).

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html
Other 9.2.22 Updates

Post-vaccination observation period

- Vaccination providers, particularly when vaccinating adolescents, should consider observing vaccine recipients for 15 minutes after vaccination. If syncope develops, patients should be observed until symptoms resolve.

- Additionally, providers should consider observing people with the following medical histories for 30 minutes after COVID-19 vaccination to monitor for allergic reactions:
  - Allergy-related contraindication to a different type of COVID-19 vaccine
  - Non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine.
  - Anaphylaxis after non-COVID-19 vaccines or injectable therapies

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html
PFIZER-BIONTECH COVID-19 VACCINATION SCHEDULE AND DOSING
FOR NON-IMMUNOCOMPROMISED POPULATIONS

See the Pfizer-Biontech 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.

illinoisvaccinates.com
PFIZER-BIONTECH COVID-19 VACCINATION SCHEDULE AND DOSING
FOR IMMUNOCOMPROMISED POPULATIONS

Pfizer-BioNTech
Ages 6 months–4 years
dose/injection volume: 3 μg/0.2 mL
Primary Dose: Maroon Cap

In 3 weeks
PRIMARY DOSE 1
3 μg/0.2 mL

In at least 8 weeks
PRIMARY DOSE 2
3 μg/0.2 mL

In at least 3 months
PRIMARY DOSE 3
3 μg/0.2 mL

In at least 12 months
BOOSTER DOSE 4
10 μg/0.2 mL

Pfizer-BioNTech
Ages 5 years–11 years
dose/injection volume: 10 μg/0.2 mL
Primary Dose: Orange Cap

In 3 weeks
PRIMARY DOSE 1
10 μg/0.2 mL

In at least 4 weeks
PRIMARY DOSE 2
10 μg/0.2 mL

In at least 3 months
PRIMARY DOSE 3
10 μg/0.2 mL

In at least 12 months
BOOSTER DOSE 4
10 μg/0.2 mL

Pfizer-BioNTech
Ages 12 years–17 years
dose/injection volume: 30 μg/0.5 mL
(Vials not used)
Primary Dose: Gray Cap
Bivalent Booster: Gray Cap (gray label)

In 3 weeks
PRIMARY DOSE 1
30 μg/0.5 mL

In at least 4 weeks
PRIMARY DOSE 2
30 μg/0.5 mL

In at least 2 months
PRIMARY DOSE 3
30 μg/0.5 mL

In at least 12 months
BIVALENT
30 μg/0.5 mL

Pfizer-BioNTech
Ages 18 years and older
dose/injection volume: 30 μg/0.5 mL
(Do NOT mix before use)
Primary Dose: Gray Cap
Bivalent Booster: Pfizer Gray Cap (gray label) or MODERNA Dark Blue Cap (gray label)

In 3 weeks
PRIMARY DOSE 1
30 μg/0.5 mL

In at least 4 weeks
PRIMARY DOSE 2
30 μg/0.5 mL

In at least 2 months
PRIMARY DOSE 3
30 μg/0.5 mL

In at least 12 months
BIVALENT
60 μg/1.0 mL

* 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.

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).

4 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–14 years, especially for males ages 12–17 years. Source: CDC

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

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MODERNA COVID-19 VACCINATION SCHEDULE AND DOSING
FOR NON-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.

† 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 12–39 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.

illinoisvaccinates.com
MODERNA COVID-19 VACCINATION SCHEDULE AND DOSING
FOR IMMUNOCOMPROMISED POPULATIONS

Modern
Ages 6 months–5 years
Dose/injection volume
(Do NOT dilate before use)
Primary Dose:
Blue Cap (magenta label)

Modern
Ages 6 years–11 years
dose/injection volume
(Do NOT dilate before use)
Primary Dose:
Blue Cap (purple label)

Modern
Ages 12 years–17 years
dose/injection volume
(Do NOT dilate before use)
Primary Dose:
Red Cap (blue label)
PSLER Bivalent Booster:
Gray Cap (gray label)

Modern
Ages 18 years and older
dose/injection volume
(Do NOT dilate before use)
Primary Dose:
Red Cap (blue label)
Bivalent Booster:
MODERN Dark Blue Cap (gray label) or
PSLER Gray 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.
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 12–29 years. Source: CDC

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

illinoisvaccinates.com
OTHER COVID-19 VACCINATION SCHEDULE AND DOSING
FOR NON-IMMUNOCOMPROMISED POPULATIONS

Janssen (J&J)
Ages 18 years and older
dose/injection volume
0.5 mL

Booster:
Pfizer Grey Cap (gray label) or
Moderna Dark Blue Cap (gray label)

Novavax
Ages 12 years–17 years
dose/injection volume
0.5 mL

Booster:
Pfizer Gray Cap (gray label)

Novavax
Ages 18 years and older
dose/injection volume
0.5 mL

Booster:
Pfizer Grey Cap (gray label) or
MODERNA Dark Blue Cap (gray label)

FOR IMMUNOCOMPROMISED POPULATIONS

Janssen (J&J)
Ages 18 years and older
dose/injection volume
0.5 mL

Primary Dose:
Pfizer’s Grey Cap
Moderna’s Red Cap (pink label)
Moderna’s Blue Cap (purple label)
Booster:
Pfizer Grey Cap (gray label) or
MODERNA Dark Blue Cap (gray label)

All charts are available at illinoisvaccinates.com/resources

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

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

▶ Moderna
  ▶ Trainings [link](#)
  ▶ Office hours and regional contacts [link](#)

▶ Pfizer
  ▶ Trainings [link](#)
Resources

▸ Updated 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
  ▸ On pediatric COVID-19 vaccines here
  ▸ On bivalent vaccines here (available in English and Spanish)

▸ AAP dosing guide for when a child has birthdays in between doses here
Friday, September 23rd from 8am-12:15pm

Register at illinoisvaccinates.com/bootcamps
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
- 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