San Francisco’s COVID19 Immunization Program is strong because of your public service. Thank you for your partnership. This is a resource with information and guidance on COVID19 Vaccine Program Administration – it is updated regularly to help you stay current.

**highlighted contents:** (click to jump to section, use [link](#) to return here)

- program updates
- vaccine temperatures
- “no missed opportunities”

**vaccines:**
- pfizer
- moderna
- janssen

**program faqs and key resources:**
- beyond use dates vs. expiration dates
- mixed series, VAERS
- guidance table: vaccine administration
- cultural competency resources
- reporting on race
- vaccine planning timeline

**what’s new?**

**program updates:**
- new requirements (Public Health Orders)
- dates of ACIP, FDA Advisory meetings
- preparing for children ages 5-11

**vaccinator resources:**
- CalVaxGrant: deadline extended until Dec. 17
- myTurn flu, volunteer resources

**storage and handling:**
- Pfizer: preparing for expanded eligibility (ages 5-11)
- preview of three different NDCs based on age / diluents
- Moderna shelf-life extension imminent
- (keep vaccine, label “DO NOT USE”), consult expiry tracker

**vaccine administration:**
- boosters, eligibility and guidance
what’s coming up:

<table>
<thead>
<tr>
<th>Mark Your Calendar</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACIP - discussing Moderna 3rd dose (&lt;agenda</td>
</tr>
<tr>
<td>FDA Advisory Committee Mtg on Pfizer for Children 5 - 11</td>
</tr>
<tr>
<td>ACIP - agenda forthcoming</td>
</tr>
<tr>
<td>estimated timeline - jump to it here</td>
</tr>
</tbody>
</table>

resources

- New Vaccine Eligibility Chart
- Vaccine Administration Guidance
- Summary Document of Clinical Considerations
- Dr. Tomás Aragon’s Webinar on boostes: Slides
- myCAvax trainings for support
- CDC Clinician Outreach Communication Activity (COCA) Call: coadministration - flu & covid vaccines
- other COCA calls
- patient resources
- order free brochures for your patients
- Collection of resources from National Academy of Medicine (NAM) and in Spanish

Guidance Document

<table>
<thead>
<tr>
<th>Guidance Document</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Requirement: Requesting Mobile Phone &amp; Email</td>
<td>CDPH</td>
</tr>
<tr>
<td>Adult Care Facilities / Direct Worker Requirement</td>
<td>CDPH</td>
</tr>
<tr>
<td>Helping patients access digital records (more here)</td>
<td>CDPH</td>
</tr>
<tr>
<td>Coadministration Tips</td>
<td>CDPH</td>
</tr>
<tr>
<td>Upcoming Expiration Vaccine Dates</td>
<td>CDC</td>
</tr>
</tbody>
</table>

is this guide helpful to you?
are there topics you’d like covered in detail?
do you need support?
mullane.ahern@sfgov.org

relevent incrementalism is working — thank you!

October 15, 2021
**vaccine temperatures**

- **log temperatures** twice a day
- Keep records for three years

**upon arrival of vaccine:**
- Check temperatures and log
- Check and count ancillary kits

  Please, never refuse shipments of vaccine even if something is wrong.

- Accept the order
- Store in an appropriate unit and report discrepancies immediately
- Work with the City to redistribute, if necessary
- Report Ancillary Kit issues to FDA

**vaccine manufacturers**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Phone</th>
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<tbody>
<tr>
<td>Pfizer</td>
<td>800-438-1985</td>
</tr>
<tr>
<td>Moderna</td>
<td>866-663-3762</td>
</tr>
<tr>
<td>Janssen</td>
<td>800-565-4008</td>
</tr>
</tbody>
</table>

**temperature excursions**

Temperature excursions or inappropriate storage conditions require immediate action:

1. Document the excursion on your temperature log using this worksheet
2. Report Excursions in myCAvax
3. Contact manufacturer(s) for guidance using phone numbers above
4. Label affected vaccines “DO NOT USE pending guidance from manufacturer.”
5. Place them apart from other vaccines (storing appropriately), do not discard.

**appropriate temperature ranges:**

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Range</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Room Temperature</td>
<td>8°C to 25°C</td>
<td>46°F to 77°F</td>
</tr>
<tr>
<td>Refrigeration</td>
<td>2°C to 8°C</td>
<td>36°F to 46°F</td>
</tr>
<tr>
<td>Freezer Temp</td>
<td>-25°C to -15°C</td>
<td>-13°F to 5°F</td>
</tr>
<tr>
<td>ULT Freezer Temp</td>
<td>-90°C to -60°C</td>
<td>-112°F to -76°F</td>
</tr>
<tr>
<td>Thermal Shipper Temp</td>
<td>-96°C to -60°C</td>
<td>-141 to -76°F</td>
</tr>
</tbody>
</table>
### Daily Reporting Requirements

<table>
<thead>
<tr>
<th>Requirement</th>
<th>System(s)</th>
<th>Frequency</th>
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<tbody>
<tr>
<td>Storage Unit Temp Log</td>
<td>Temperature Log</td>
<td>2x/day</td>
</tr>
<tr>
<td>Inventory On Hand</td>
<td>VaccineFinder</td>
<td>Daily, even if 0</td>
</tr>
<tr>
<td>Doses Administered</td>
<td>CAIR / MyTurn / EHR / EMR</td>
<td>Daily</td>
</tr>
<tr>
<td>Redistributions or Transfers</td>
<td>myCAvax</td>
<td>Any day they occur</td>
</tr>
<tr>
<td>Shipping incidents, excursions, wastage</td>
<td>myCAvax</td>
<td>Any day they occur</td>
</tr>
<tr>
<td>Adverse Events</td>
<td>VAERS, DPH</td>
<td>Any day they occur</td>
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</tbody>
</table>

**Important Note:**
- Recording race/ethnicity of each patient is required – learn more here.
- Clinics or events using coolers for vaccine storage must check and log vaccine.

**Required Training Before Receiving Vaccine**

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Training Time</th>
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<tbody>
<tr>
<td>myCAvax</td>
<td>1 Hour (CDPH)</td>
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<tr>
<td>Pfizer Vaccine</td>
<td>40 Minutes (CDC)</td>
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<tr>
<td>Moderna</td>
<td>20 Minutes (CDC)</td>
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<tr>
<td>Janssen</td>
<td>20 Minutes (CDC)</td>
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</tbody>
</table>

**Getting Started:**
- Sign your organization up for CAIR (immunization registry).
- Decide roles and responsibilities: everyone involved needs training!
- We can help with myCAvax.
- Review one-pager on critical systems.

### Digital Data Loggers:

Storage units must be equipped with a digital data logger; these devices with a buffered probe provide more accurate readings.

**Ultra-Cold Devices:** For accurate ultra-cold temperature monitoring, use an air probe or a probe designed specifically for ultra-cold temps with the data logger.

**Backup Devices:** Providers must have at least one backup data logger in case a primary device breaks or malfunctions, and for vaccine redistribution.

**Certificates of Calibration:** Always use data loggers with a current and valid certificate of calibration testing. See CDC’s Vaccine Storage and Handling Toolkit.
vaccine administration

Weekly trainings occur on systems like myCAvax and myTurn. Resources like injection safety and training for non-traditional vaccinators can aid any site.

vaccination: no missed opportunities

Never miss a vaccination opportunity! Vaccinate every eligible person who presents at a vaccination site—even if it means puncturing a vial at the end of the day.

Vaccinate family members or friends who accompany patients to medical visits—even if they are not established patients at the practice. For instance, a parent or sibling that brings a child to a pediatric appointment may not be vaccinated—please ask, and offer to vaccinate!

best practices

- Schedule the second appointment, send a reminder text with VaxText. Completing the series is essential.
- Rotate vaccine inventory weekly and check expiration dates.
- Coadminister COVID vaccine with other vaccines.
- Create accessible, inclusive spaces for people with disabilities, remove access and communication barriers.
- Suggest patients take a photo of vaccination card, keep the original safe.
- Accept verbal, written, or video consent from parents or guardians for minors.
- Engage! Get comfortable having important conversations with patients about their concerns, and sharing your great work in the community.
- If a patient is unhoused, enter the city/county of residence in CAIR so their digital vaccine record may be as complete as possible.
- Encourage pregnant patients to enroll in CDC’s v-safe program.
- Maintain a vaccine management plan.
- Let us know when you need guidance or support, or what practices are successful for you, we love hearing about the incredible work of our community partners!
**Pfizer-BioNTech COVID-19 Vaccine**  (Comirnaty) (koe-mir-na-tee)

mRNA vaccine for prevention of COVID-19

Approved by FDA as Comirnaty for use in persons ages 16 and older, interchangeable with Pfizer-BioNTech Vaccine.

Continue to administer pursuant to **Emergency Use Authorization** (EUA), which recommends Pfizer for persons 12+ as follows:

<table>
<thead>
<tr>
<th><strong>Primary Series</strong></th>
<th><strong>Additional Dose</strong></th>
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</thead>
<tbody>
<tr>
<td>2 doses</td>
<td>a third dose (ie, additional dose) is authorized for ages 12+ with immunocompromising conditions</td>
</tr>
<tr>
<td>Separated by 21 days</td>
<td>- 28 days or more after primary series</td>
</tr>
<tr>
<td>Must be mixed with diluent</td>
<td>- a series started with Pfizer should be completed with Pfizer</td>
</tr>
<tr>
<td>5-6 doses / vial</td>
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</tbody>
</table>

**Mixed Vaccine**

- keep 2°C to 25°C
- **use within 6 hours** then discard unused vaccine
- minimize exposure to light
- avoid direct sunlight, UV light

**Arrives Frozen ❄️ Thaw Time**

**Refrigerator:**
- unpunctured vials up to 31 days
- thaw in fridge unless needed immediately

**Room Temperature /Immediate Use:**
- up to 2 hours including thaw time
- do not keep unpunctured vials at room temperature for more than 2 hours

**Key Documents**

<table>
<thead>
<tr>
<th><strong>Key Documents</strong></th>
<th><strong>FDA package insert</strong></th>
<th><strong>CDC Vaccine Preparation</strong></th>
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</thead>
<tbody>
<tr>
<td>Standing Orders</td>
<td>FDA Fact Sheet</td>
<td>Shelf Life Extended 8/21</td>
</tr>
<tr>
<td>Vaccine Administration</td>
<td>Clinical Considerations</td>
<td>Local Reactions</td>
</tr>
<tr>
<td>Low Dead-Volume Syringes and/or Needles</td>
<td>Fact Sheet for Caregivers</td>
<td>CAHAN for mRNA vaccines</td>
</tr>
</tbody>
</table>
### Pfizer-BioNTech COVID-19 Vaccine (Comirnaty) (koe-mir-na-tee)

mRNA vaccine for prevention of COVID-19

---

**storage and handling continued**

keep vaccine stored at the coldest possible temperatures you can support, tracking dates to optimize vaccine shelf life:

**pfizer thermal shipper:**
- Store in original thermal shipper for 30 days
- open no more than 2x day /up to 3 min when open
- Label vaccine with Beyond Use Date
- Refresh dry ice every 5 days
- Transfer doses to freezer or fridge

**pfizer in freezer:**
- in the fridge for up to 2 weeks (label BUD 14 days)
- Transfer remaining doses to fridge

**refrigerator:**
- Up to 5 days (BUD 120 hours)

**do NOT refreeze thawed vaccine**
Never freeze diluent

**see expected changes with NDCs**

---

**Pfizer Shelf Life Extension:**

Extends shelf life from 6 to 9 months for vaccine stored in ultra cold temps of -90°C to -60°C.

applies to cartons and vials with expiry date printed on the label

August 2021 – Feb 2022

What is **NOT** eligible for extension?
- frozen vials stored at -25°C to -15°C
- refrigerated vials at 2°C to 8°C

this is based on stability data from the past nine months.

......pretty cool!
Moderna COVID-19 Vaccine
mRNA vaccine for prevention of COVID-19

Recommended for use under EUA to prevent COVID-19 in persons 18+

Primary Series:
- 2 Doses
- 28 days apart
- do not mix with diluent
- max 15 doses / vial

Additional Dose
- a third dose (ie, additional dose) authorized for ages 18+ with immunocompromising conditions:
  - 28 days or more after primary series
  - series started with Moderna should be completed w Moderna

Moderna Storage
- arrives frozen, can be stored frozen until expiration
- scan QR / use expiry checker

Store Frozen Unpunctured:
- in the fridge for up to 30 days
- a room temp up to 24 hrs

Moderna BUD Label

Thaw Time
- ~3 hrs in fridge
- ~1.5 hrs room temp

Once Punctured:
- use within 12 hours
- Keep btwn 2°C to 25°C

Moderna shelf-life extension expected imminently
- do not throw away! Label “DO NOT USE” and check expiry tracker!

<table>
<thead>
<tr>
<th>Moderna Vaccine Administration</th>
<th>Emergency Use Authorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDC Summary of Recent Changes</td>
<td>Standing Orders</td>
</tr>
<tr>
<td>Local Reaction Information</td>
<td>CAHAN for mRNA vaccines</td>
</tr>
<tr>
<td>Fact Sheet</td>
<td>Fact Sheet for Caregivers</td>
</tr>
</tbody>
</table>
where can providers find information on mixed series dose administration, or instructions on when to repeat a dose?

this is in the CDC’s Clinical Considerations, updated as of September 27, 2021. See Appendix A on Vaccine Administration Errors and Deviations, follow CDC recommendations on when to report to VAERS.

Janssen COVID-19 Vaccine (Johnson & Johnson)
Recommended under EUA to prevent COVID19 in persons 18+

Schedule: One Dose
- 5 Doses / Vial
- Do Not Mix With Diluent
- Scan QR code to find expiration date use expiry checker

Resources
- Fact Sheet
- Fact Sheet for Caregivers
- CDC Resources
- Vaccine Administration
- Standing Orders

Store in Refrigerator
Do Not Store Frozen
Once Punctured:
- Keep refrigerated up to 6 hours
- Or room temp up to 2 hours

program faqs and key resources:
what is the difference between “beyond use date” and “expiration date”?  

**beyond use date** is determined by storage and preparation conditions. Example: Pfizer moved from freezer to the fridge has a BUD of 31 days from the date it is moved to fridge. After 31 days, you must dispose of the vaccine. **Label and track it!**

**expiration** is the date by which the vaccine must be used, determined by the time of manufacture. Pay attention to BOTH the BUD and expiration dates. Report to VAERS if you administer past either date.

Modernafact Sheet  Pfizer BUD label

what’s the recommendation for individuals who believe they may have COVID19?  

Here are self-isolation instructions for individuals who likely have COVID19.
what’s the difference between a “booster shot” and an “additional dose”?

A **booster shot** is administered when a person has completed their vaccine series and protection against the virus has decreased over time. Additional doses are administered to people with moderately to severely compromised immune systems. This **additional dose** of an mRNA-COVID19 vaccine is intended to improve immunocompromised people’s response to their initial vaccine series. Contact immunocompromised patients for an additional dose.

**Who is eligible?** A single booster dose of Pfizer is authorized at least 6 months after completion of primary series in individuals:
- age 65 years+;
- age 18 - 64 at high risk of severe COVID19; and
- age 18 - 64 whose frequent institutional or occupational exposure puts them at high risk of serious complications of COVID19.

Record both in “other” section → more to come on Moderna & Janssen boosters soon.

### Guidance Document

<table>
<thead>
<tr>
<th>Guidance Document</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine Eligibility Chart</td>
<td>CDPH</td>
</tr>
<tr>
<td><strong>Booster Dose Readiness Checklist</strong></td>
<td>CDPH</td>
</tr>
<tr>
<td>Booster Doses Are Not Additional Doses</td>
<td>CDPH</td>
</tr>
<tr>
<td>Clinical Considerations (updated Sept 27)</td>
<td>CDC</td>
</tr>
<tr>
<td>Booster / Additional Shot FAQs</td>
<td>CDC</td>
</tr>
</tbody>
</table>

**should people with a history of COVID19 be vaccinated?**

**YES.** CDC recommends a complete vaccination series for persons with a history of SARS-CoV-2 once they have recovered from acute illness and meet all criteria for discontinuing isolation. Persons with prolonged COVID symptoms should be offered vaccination.
what’s up with digital vaccine records?

Patients can access vaccine records through the Digital COVID19 Vaccine Record Portal after their vaccination information is submitted to CAIR. The portal provides vaccine recipients a QR code to access digital vaccination records on their mobile device.

details and support: the FAQ page and troubleshooting page

It is not a perfect system. Names can be misspelled or other errors may appear that a person may need help correcting. Providers can send questions and requests regarding digital vaccine records to DCVRRemediation.Requests@cdph.ca.gov.

5 resources to promote equity in healthcare

1. how to provide culturally competent care for patients with disabilities
2. improve health equity with culturally competent care for BIPOC parents
3. healthcare guidance for transgender & gender nonconforming individuals
4. patient care and cultural awareness
5. adverse childhood experiences

<table>
<thead>
<tr>
<th>Guidance Document</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccinating Homebound Persons</td>
<td>CDC</td>
</tr>
<tr>
<td>Curbside or Drivethrough Clinics</td>
<td>CDC</td>
</tr>
<tr>
<td>Drive Thru Site Accessibility Fact Sheet</td>
<td>Pacific ADA Center</td>
</tr>
<tr>
<td>Accessibility Planning Checklist</td>
<td>Pacific ADA Center</td>
</tr>
<tr>
<td>Immunization Strategies for Healthcare Providers</td>
<td>CDC</td>
</tr>
</tbody>
</table>
race and ethnicity

5 reasons why

it’s important to always ask about race, ethnicity, and comorbidities when administering vaccine and health services

this information helps to:

1. ensure vaccine is distributed **equitably**
2. assess gaps in immunization coverage
3. support interventions to address health disparities
4. improve data quality and accuracy, **and**
5. recording race + ethnicity are required for every patient receiving COVID19 vaccine when reporting doses administered

**consistency is key**

**first question:**

are you Hispanic / Latinx / Latino/a?

**second question:**

what race are you?

for individuals who identify as Filipinx / Filipino/a, select “Asian” for the race category

for individuals who identify as Middle Eastern / North African / MENA descent, select “white” for race category

**specificity matters**

• avoid selecting “other” as a race category
• avoid selecting “unknown” as ethnicity
• do not select “Multiracial” if a person identifies with two+ ethnicities in same OMB racial category (ie: Chinese and Filipino; Italian and Egyptian)
• do not select “Multiracial” if a person affirms Hispanic identity and selects only one OMB racial category (ie white, Black, Asian, AI/AN, NHPI)
is COVID19 vaccination safe for someone who’s pregnant?

yes. vaccination against COVID19 is the safest possible choice a person could make before, during, or after pregnancy. this Conversation Guide for Clinicians by ACOG is an excellent resource. please review recommendations by CDC, and by ACOG.

pregnant people are at high risk for severe COVID disease. acute respiratory infection during pregnancy causes adverse outcomes, especially preterm birth. these risks are greater for people who are Black, indigenous, Latinx, + other people of color. below are five safety facts for patients:

1. COVID19 vaccines do not cause infection in the pregnant person or the fetus. A growing body of data demonstrate the safety of such use, including observing pregnant people enrolled in V-Safe, VAERS, and CDC’s v-safe pregnancy registry.
2. side effects are a normal reaction to the vaccine.
3. safety monitoring and clinical research is ongoing.
4. vaccination of pregnant people generates an immune response. reports indicate potential protection against COVID19 for neonates + infants.
5. early reports + data show mRNA vaccines during pregnancy are effective.
Pfizer: preparing for ages 5-11

- an Emergency Use Authorization request for the Pfizer-BioNTech vaccine for children ages 5-11 is expected to be approved before the other vaccines.

- **regulatory timeline:** Advisory Committees to the FDA and CDC are to meet on October 26 (FDA’s Vaccines and Related Biological Products Advisory Committee) and November 2-3 (CDC’s Advisory Committee on Immunization Practices).

- pending FDA authorization, CDC recommendations, and independent review of the Western States Safety Review Workgroup, pediatric providers should be ready to vaccinate this age group in the first week of November.

- the Pfizer COVID-19 vaccine for 5-to-11-year-olds will be a new product with new packaging, new product configuration (10-dose vial), different dosage and injection volume, and have a new National Drug Code (NDC).

- current product for adults & adolescents cannot be used in children under 12.

---

**New Product**

- The Pfizer COVID-19 vaccine for 5-to-11-year-olds will be a new product with new packaging, new product configuration (10-dose vial), different dosage and injection volume, and have a new National Drug Code (NDC).

- Current product for adults and adolescents cannot be used in children under 12 years of age.
FDB deliberation and anticipated authorization
Subject to change; may be updated as additional information becomes available

<table>
<thead>
<tr>
<th></th>
<th>Approved / Authorized</th>
<th>Jun '21</th>
<th>Jul</th>
<th>Aug</th>
<th>Sep</th>
<th>Oct</th>
<th>Nov</th>
<th>Dec</th>
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<tbody>
<tr>
<td><strong>Pfizer-BioNTech</strong></td>
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<tr>
<td>235,518,908 doses</td>
<td>EUA: 16+ (12/20)</td>
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<td>EUA: 12-15 (5/21)</td>
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<td></td>
<td>EUA: Additional Dose (8/21)</td>
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<td></td>
<td>EUA: Booster (9/21)</td>
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<td>FDA approval: 16+ (7/21)</td>
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<td><strong>Upcoming Decisions:</strong></td>
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<td>10/28 VRBPAC</td>
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<td>10/27-28 FDA authorization¹</td>
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<td>10/30 WSSSRW</td>
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<tr>
<td><strong>Moderna</strong></td>
<td>EUA: 18+ (12/20)</td>
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<td>153,216,702 doses</td>
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<td><strong>Upcoming Decisions:</strong></td>
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<td>10/16 FDA authorization¹</td>
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<tr>
<td><strong>Janssen (J&amp;J)</strong></td>
<td>EUA: 18+ (2/21)</td>
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<td>15,225,611 doses</td>
<td><strong>Upcoming Decisions:</strong></td>
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<td>10/14-15 VRBPAC</td>
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<tr>
<td></td>
<td>10/16 FDA authorization¹</td>
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<tr>
<td><strong>Mix &amp; Match Boosters</strong></td>
<td>EUA: Booster</td>
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¹ FDA deliberation and anticipated authorization
² Subject to change; may be updated as additional information becomes available

PRELIMINARY; AS OF OCTOBER 13, 2021