COVID-19 VACCINE UPDATES FOR SCC PROVIDERS
COVID-19 Vaccination Planning Overview

- Vaccination Status
- Clinical Updates
- Q&A
- Allocation & Ordering Updates
- Storage and Handling Updates
- Other Resources
- Q&A
Santa Clara County Vaccination Status
COVID-19 Vaccinations Among Santa Clara County Residents
Last updated on November 3, 2021

Residents Ages 12+ With Completed Vaccination: 1,463,696
Percent of Residents Ages 12+ With Completed Vaccination: 85.3%
Residents All Ages With Completed Vaccination: 1,463,696
Percent of Residents All Ages With Completed Vaccination: 73.3%
Number of Residents with Booster Dose: 162,205

COVID-19 Vaccine Doses Administered Over Time

Values for the most recent 3 days are preliminary

Last updated: 11/4/2021
Clinical Updates
Timeline for Vaccine Authorization

10/21/21
CDC formally recommends Moderna and Janssen boosters, "mix and match"

10/26/21
FDA advisory committee meeting on Pfizer for 5-11 yos

10/29/21
FDA authorizes Pfizer for 5-11 yos

11/2/21
ACIP, CDC, and WSSSRW formally recommend Pfizer for 5-11 yos

2022(?)*
Moderna submits data for 6-11 yo EUA [delayed]

1/2022*
FDA reviews EUA for Moderna 12-17 yo [delayed]

*dates subject to change

Last updated: 11/4/2021
## Booster Eligibility

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Eligibility</th>
<th>Dose</th>
<th>Interval</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer</td>
<td>• 65 years and older&lt;br&gt;• 18 years and older residents of long-term care settings</td>
<td>0.3 mL (30 ug) [same as primary series]</td>
<td>At least 6 months after the primary series</td>
<td>• FDA Authorized&lt;br&gt;• CDC Recommended</td>
</tr>
<tr>
<td>Moderna</td>
<td>• 18-64 years old with underlying medical conditions&lt;br&gt;• 18-64 years old who work in high-risk settings</td>
<td>0.25 mL (50 ug) [half the dose of the primary series]</td>
<td>At least 2 months after the initial dose</td>
<td></td>
</tr>
<tr>
<td>Janssen</td>
<td>• 18+ yo</td>
<td>0.5 mL [same as initial dose]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: A booster dose may be administered as early as 4 days prior to the recommended interval. If the booster is administered earlier than the 4-day grace period, the dose does NOT need to be repeated.
### Heterologous Booster Recommendations

- **Pfizer**: Full Dose, Half Dose, or Janssen Full Dose
  - Must meet Pfizer booster eligibility
  - 6 months

- **Moderna**: Half Dose, Full Dose, or Janssen Full Dose
  - Must meet Moderna booster eligibility
  - 6 months

- **Janssen**: Full Dose, Half Dose, or Janssen Full Dose
  - All 18+ years eligible
  - 2 months

Note: ACIP/CDC do not state a product preference for booster dose

Last updated: 11/4/2021
Boosters for Immunocompromised People

mRNA Vaccines

- **Primary Series Dose 1**
  - Pfizer: 21 days
  - Moderna: 28 days

- **Primary Series Dose 2**

- **Additional Dose**
  - Must be *same product and dose* as primary series

- **Booster Dose**
  - May be heterologous

  - Pfizer: 21 days
  - Moderna: 28 days

Janssen

- **Initial Dose**
  - 2 months

- **Booster Dose**
  - May be heterologous

  - Janssen recipients should not receive more than 2 COVID-19 vaccine doses

Last updated: 11/4/2021
## Boosters for People Vaccinated Outside the United States

### WHO-authorized vaccines†
- Pfizer-BioNTech
- Moderna
- Janssen
- AstraZeneca/SKBio
- Serum Institute of India
- Sinopharm
- Sinovac

### FDA-authorized vaccines
- **Pfizer-BioNTech**
  - Primary series for 5 to < 16 yo
  - 3rd dose for ≥ 12 yo in certain immunocompromised patients
  - Booster dose for ≥ 18 yo in certain patients
- **Moderna**
  - Primary series for ≥ 18 yo
  - 3rd dose for ≥ 18 yo in certain immunocompromised patients
  - Booster dose for ≥ 18 yo in certain patients
- **Janssen**
  - Primary vaccination for ≥ 18 yo
  - Booster dose for ≥ 18 yo

### FDA-approved vaccines
- **COMIRNATY® by Pfizer-BioNTech**
  - ≥ 16 yo only

### Action
- May receive booster dose if eligible
- Currently no guidance for booster dose

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*The FDA-approved Pfizer-BioNTech product COMIRNATY® and the FDA-authorized Pfizer-BioNTech COVID-19 vaccine have the same formulation and can be used interchangeably.
† For complete list visit https://www.who.int/teams/regulation-prequalification/eul/covid-19

Last updated: 11/4/2021
Are children at risk for COVID-19 infection?

- **Children 5-11 are just as likely to get infected as adults**
  - Nearly 2 million+ cases nationwide
  - At least 94 children have died of COVID-19
  - More than 8,000 children hospitalized
    - 1/3 of those children ended up in the ICU
    - Rates are higher in Hispanic, Black and Native American children
  - Children can transmit COVID to other children and adults
  - Long COVID has been reported in children

Last updated: 11/4/2021
Eligibility for a Pediatric COVID-19 Vaccine

• All children ages 5 years to 11 years
• Children can get vaccinated even if:
  • Child has food or other seasonal allergies
  • Child has been infected previously with COVID-19
  • Child has other medical conditions such as diabetes, asthma

Last updated: 11/4/2021
About the Vaccine

• Only the Pfizer vaccine is authorized for children
  • Children’s dose is smaller, 1/3 the dose for adults
  • 2 doses, 21 days apart
  • 90% effective in preventing symptomatic disease
  • Mild side effects common but resolve in a day or two.
• Other vaccinations can be given at the same time
  • Flu shot
  • Childhood vaccinations (i.e. Tdap, MMR)
Children 5-11 years of age are authorized to receive a 2-dose series of the Pfizer vaccine 10 ug (0.2 mL), 21 days apart

- NOT eligible for a booster dose or an additional dose for immunocompromised children

Children who turn 12 between their first and second dose:

- CDC: administer the age-appropriate 30 ug (12+ yo formulation) Pfizer vaccine for their second dose to complete the series
- FDA: administer either the 10 ug (5-11 yo formulation) or the 30 ug for either dose
- The child is considered fully vaccinated under either circumstance

Please see the CDC Interim Clinical Considerations for the COVID-19 Vaccine for more detailed guidance

Last updated: 11/4/2021
Inadvertent Administration of COVID-19 Vaccine

- **Wrong age?**
- **Wrong formulation?**

Follow CDC Clinical Guidance

<table>
<thead>
<tr>
<th>Age</th>
<th>Unauthorized age group</th>
<th>Formulation and dosage</th>
<th>Do not repeat dose?</th>
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<tr>
<td></td>
<td>If received dose at age less than 5 years, do not give another dose at this time.†</td>
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Last updated: 11/4/2021
Minor Consent for Vaccination

- Sample CDPH Consent Form Link
  - Can choose to use sample or a form of your preference

Options for Consent

Persons younger than 18 years must have parental or guardian consent given by a legally authorized representative (parent or guardian). An emancipated minor may consent for him/herself. Currently, only the Pfizer vaccine has received Emergency Use Authorization for people under 18.

Allowable consent includes:

- Parent/guardian accompanies the minor in person.
- If the parent/guardian cannot accompany the minor, a signed written consent is acceptable. The written consent must verify the parent/guardian has been provided the Pfizer EUA Fact Sheet (PDF).
- Phone or video consent is possible if the parent/guardian confirms that they have been provided the Pfizer EUA Fact Sheet (PDF) or the Fact Sheet is read to the parent/guardian.

To learn more about risks, benefits, and side effects of the Pfizer vaccine, check the CDPH website Get the Facts on Vaccines (ca.gov) and/or read the U.S. Food and Drug Administration’s Fact Sheet for Recipients and Caregivers (PDF).
Clinical Section – Q&A
Pediatric Pfizer Allocation & Ordering Update
Pediatric Pfizer – on Allocation

- Pediatric Pfizer vaccine remains on allocation for the time being
- SCC allocation for week two of ordering not yet released

Key Messages
- Order weekly via myCAvax small orders feature
- Please do not over order. Order what you need; use what you order.
- The ped vaccine shelf life is shorter than the adult Pfizer product
- Manage inventory accordingly

Last updated: 11/4/2021
myCAvax Vaccine Ordering

### Vaccine Ordering

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Order Type</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pediatric Pfizer</strong></td>
<td>Pre-order period: Standard Order</td>
</tr>
<tr>
<td>(5-11)</td>
<td>Open-order period: Small Orders</td>
</tr>
<tr>
<td><strong>Pfizer (12+)</strong></td>
<td>Small Orders</td>
</tr>
<tr>
<td><strong>Moderna</strong></td>
<td>Small Orders</td>
</tr>
<tr>
<td><strong>Janssen</strong></td>
<td>Small Orders</td>
</tr>
</tbody>
</table>

Please place all orders using small orders feature. If you need more than the small orders quantity cap, please indicate your need in the comments section.

Last updated: 11/4/2021
Storage & Handling Updates
# Pfizer 5-11 Formulation Storage & Handling

<table>
<thead>
<tr>
<th>Unpunctured Vials</th>
<th>Storage Conditions</th>
<th>Shelf-Life</th>
</tr>
</thead>
</table>
| **Ultra-low Temperature**  
-90°C to -60°C (-130°F to -76°F) | 6 months from printed manufacturer date |
| **Frozen**  
-25°C to -15°C (-13°F to 5°F) | **Not permitted! Do not store in freezer.** |
| **Fridge**  
2°C to 8°C (36°F to 46°F) | 10 weeks  
- Thawed vials **may not be returned** to ULT or placed in the freezer |
| **Room Temperature**  
8°C to 25°C (46°F to 77°F) | 12 hours |

<table>
<thead>
<tr>
<th>Punctured / Diluted Vials</th>
<th>Storage Conditions</th>
<th>Shelf-Life</th>
</tr>
</thead>
</table>
| **Fridge**  
2°C to 8°C (36°F to 46°F) | 12 hours |
| **Room Temperature**  
8°C to 25°C (46°F to 77°F) | 12 hours |
The printed manufacturer date on the vials is **NOT** the expiration date

Vaccines should not be used, regardless of storage condition, after 6 months from the printed manufacturer date
Pediatric Pfizer Ancillary Kit

- Mixing supplies: 1.5” needles, 3 mL syringes, 5 mL syringes

- Dilution: 10 mL NS vials
  - While these vials appear to contain sufficient diluent for multiple vials, they must only be used once
  - Extract 1.3 mL of diluent from each single-use NS vial
  - Discard remaining content after each use

- Administration supplies: 1” needle, 1 mL syringe
Expiration Extended!

Additional 2 months at frozen temperature only
- Extension does not apply to refrigerated Moderna

Please check and update your expirations using Moderna’s Vial Expiration Date website
- If expiration is not posted,
  - Segregate doses and mark recently “expired” doses as “DO NOT USE pending extension decision”

See updated list of LOT# not subject to expiry extension

https://www.modernatx.com/covid19vaccine-eua/providers/vial-lookup
Last updated: 11/4/2021
## COVID-19 Vaccine Product Guide

### Packaging
- **Cap Color**
  - 5-11 years old:
    - Pfizer (Pediatric): Orange cap
    - 6 doses
  - 12+ years old:
    - Pfizer: Purple cap
    - 6 doses
    - Pfizer (Comirnaty): Gray cap
    - 6 doses
  - 18+ years old:
    - Janssen (J&J): Blue cap
    - 5 doses
    - Moderna: Red cap
    - 14 (or 10) doses
- **Doses Per Vial**
  - 5-11 years old:
    - Pfizer (Pediatric): 10 doses
  - 12+ years old:
    - 1170 (or 450) doses
  - 18+ years old:
    - 95267-1055-04: 100 doses
    - 59267-1000-02: TBD
    - 59676-0580-15: TBD
    - 80777-0273-98: TBD
- **Package Size**
  - 5-11 years old:
    - 95267-1055-04: 100 doses
  - 12+ years old:
    - 59267-1000-02: TBD
  - 18+ years old:
    - 59676-0580-15: TBD
    - 80777-0273-98: TBD
- **NDC # in VPrime**
  - 5-11 years old:
    - 95267-1055-04: TBD
  - 12+ years old:
    - 59267-1000-02: TBD
  - 18+ years old:
    - 59676-0580-15: TBD
    - 80777-0273-98: TBD

### Administration
- **Diluent**
  - 5-11 years old:
    - 1.3 mL per vial
  - 12+ years old:
    - 1.8 mL per vial
  - 18+ years old:
    - 1.8 mL per vial
- **Injection Volume - Primary**
  - 5-11 years old:
    - 0.2 mL
  - 12+ years old:
    - 0.3 mL
  - 18+ years old:
    - 0.3 mL
- **Injection Volume - Booster**
  - 5-11 years old:
    - N/A
  - 12+ years old:
    - same (age 18+ only)
  - 18+ years old:
    - 0.25 mL

### Storage Limits
- **ULT (-90 to -60°C)**
  - 5-11 years old:
    - Up to 6 months
  - 12+ years old:
    - Up to 6 months
  - 18+ years old:
    - N/A
- **Thermal Shipment**
  - 5-11 years old:
    - N/A
  - 12+ years old:
    - N/A
  - 18+ years old:
    - N/A
- **Freezer**
  - 5-11 years old:
    - Up to 14 days
  - 12+ years old:
    - Up to 14 days
  - 18+ years old:
    - Up to 10 weeks
- **Refrigerator (2° to 8°C)**
  - 5-11 years old:
    - Up to 10 weeks
  - 12+ years old:
    - Up to 10 weeks
  - 18+ years old:
    - Until expiration

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**COVID-19 Vaccine Product Guide:**
- Packaging
- Administration
- Storage Limits
- Age
- Availability

Last updated: 11/4/2021

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**California COVID-19 Vaccination Program**

**IMM-1399 (10/29/21)**
Other Resources
Upcoming Pediatric Vaccine Webinars

- Townhall for Pediatric COVID-19 Vaccine Providers
  - **Friday, November 5\(^{th}\), at 11 AM PST**
    - [Click here to register](#)

- California Immunization Coalition Webinar: Updates on COVID-19 Vaccination for Children
  - **Thursday, November 4\(^{th}\), at 6 PM PST**
    - [Click here to register](#)
CDPH COVID-19 Vaccine Office Hours for Providers

- Fridays – 9:00AM to 10:00AM

  SESSION NUMBER: 145 195 9307
  SESSION PASSWORD: Immunize2021!

  Meeting Link: [Click here](https://eziz.org/covid/)

  AUDIO CONNECTION: 1-415-655-0001
  ACCESS CODE: 145 195 9307

- View archived sessions at: [https://eziz.org/covid/](https://eziz.org/covid/)

Last updated: 11/4/2021
Resources Available

- Submit 213RR for medical supply if you are running low:
  - Hand Sanitizer
  - Alcohol Swabs
  - Cotton Balls
  - Bandages
  - 1 mL Syringes
  - And more...

Last updated: 11/4/2021
Provider Resources on EZIZ.org/COVID

Program Updates

- COVID-19 Vaccination Program FAQs Updated 10/14
- Connect with Vaccine Experts – Provider Office Hours Every Friday
- myCVax Training
- Weekly Webinars and Training Calendar

Pre-Order Pfizer Vaccine for 5-11 Years of Age

- Catch-up pre-ordering is available through Friday, October 22 at 5:09 PM.
- Pre-Orders Available in myCVax
- Pre-Ordering and Anticipated Delivery Schedule

CalVaxGrant Deadline Extended to December 17!

- There's still time to apply for Grants up to $35,000 for Support of Small Practices

What barriers do you foresee in administering booster doses in the next month?

- Please email CovidCallCenter@cph.ca.gov with your responses. You’re feedback is appreciated!
- COVID-19 Vaccine Eligibility Chart | Summary of Related Guidance and Requirements
- Are You Ready for Expanded Booster Doses? – Provider Readiness Checklist
- CDPH Town Hall on Booster Dose Readiness | Slides

Now Enrolling Providers of Pediatric Services

- Benefits for Primary Care Providers
- Find Information on How to Enroll

Vaccine Management:

- List of Upcoming COVID-19 Vaccine Expiration Dates
- Ordering Vaccines | New Ordering & Distribution Cadence

Provider Support

COVID Call Center
- Email: For Program Info
- Phone: (833) 302-1245
- Hours: Mon-Fri, 8AM-4PM

myCVax Help Desk
- Email: For Technical Support
- Phone: (833) 302-1245, option 2

Vaccines

Manufacturer Contacts

My Turn
- Email: For Onboarding, Technical Support
- Help Desk: (833) 302-1245, option 4
- Mon-Pri: 7AM-7PM
- Sat-Sun: 8AM-1PM
- Clinic Translation Line: (833) 966-9363
- Mon-Pri: 8AM-2PM
- Sun-Sat: 8AM-5PM
Thank you!

Questions? Email us at: vaccinebranch@eoc.sccgov.org