

California Department of Public Health CA COVID-19 Vaccination Program



Novavax Quickinar

Friday August 12, 2022

12:30 PM – 1:00 PM

Questions?

During today's session, please use the Q&A panel to ask your questions so CDPH subject matter experts can respond directly.



Housekeeping

Reminder to Panelists:



Please mute yourself when not speaking.

Please monitor the Q&A panel for questions you may be able to answer.

Reminder to Attendees:



Today's session is being recorded. Access today's slides and archived presentations at:
<https://eziz.org/covid/education/>



For post-webinar-related questions, please email leslie.amani@cdph.ca.gov

Agenda: Friday, August 12, 2022

No.	Item	Speaker(s)	Time (PM)
1	Welcome and Introductions	Leslie Amani (Moderator)	12:30 – 12:35
2	Novavax Clinical	Priyanka Saxena, D.O. (CDPH)	12:35 – 12:40
3	Novavax Storage and Handling	Kate McHugh (CDPH)	12:40 – 12:45
4	Novavax Ordering	Christina Sapad (CDPH)	12:45 – 12:50
5	My Turn	Eric Norton (CDPH)	12:50 – 12:55
6	Wrap-up	Leslie Amani (CDPH)	12:55 – 1:00
Q&A and Thank you!			

Novavax Clinical

Priyanka Saxena, D.O., CDPH

Novavax COVID-19 Vaccine (NVX-Co2373)

- Novavax (NVX-Co2373) contains the SARS-CoV-2 recombinant spike protein and Matrix-M adjuvant
- Novavax vaccines are safe and effective
 - Clinical trial showed 90% vaccine efficacy against symptomatic Covid-19 infection during alpha predominance
 - Frequency of serious adverse events were similar in groups receiving vaccine and placebo
- Can be co-administered with other vaccines
 - Guidance regarding administration with [orthopox vaccine](#)
- Novavax is not authorized to be used as a booster dose
 - Additionally, a booster dose using any COVID-19 vaccine is not authorized for adults who receive a Novavax primary series

Novavax Considerations

- 2-dose primary series in adults 18 years of age and older, administered 3-8 weeks apart
 - A longer interval between doses may reduce the small risk of myocarditis/pericarditis
- In general, the same vaccine product should be used for all doses of the primary series
- In the following exceptional situations, a different, age-appropriate COVID-19 vaccine may be administered to complete a primary series at a minimum of 28 days from the last COVID-19 vaccine dose. No VAERS reports is required.
 - The same vaccine is not available.
 - The first dose is unknown
 - A person starts but is unable to complete a primary series with the same COVID-19 vaccine due to a contraindication.

Vaccine Timing Guide: Adolescent/Adult

COVID-19 Vaccine Timing–Adolescent/Adult

Vaccinate ALL 58

Routine Schedule

Age	Vaccine	Primary Doses	Booster Doses
12-17	Moderna–Adol/Adult	1st Dose → 4-8 weeks → 2nd Dose	
12+	Pfizer/Adol/Adult	1st Dose → 3-8 weeks* → 2nd Dose	≥5 months → 1st Booster (Ages 12-17: Pfizer) ≥4 months → 2nd Booster (Ages 50+: Moderna/Pfizer)
18+	Moderna–Adol/Adult	1st Dose → 4-8 weeks* → 2nd Dose	≥5 months → 1st Booster (Ages 12-17: Pfizer) ≥4 months → 2nd Booster (Ages 50+: Moderna/Pfizer) (If received J&J for primary and 1st booster, may consider receiving a 2nd booster of mRNA vaccine.)
18+	Janssen (J&J) Pfizer/Moderna preferred*	1st Dose → ≥2 months → 2nd Dose	
18+	Novavax	1st Dose → 3-8 weeks* → 2nd Dose	

^ An 8-week interval may be preferable for some people, especially for males 12-39 years.
 * Although use of mRNA COVID-19 vaccines is preferred, the Janssen vaccine may be offered in [some situations](#).
 View [Interim Clinical Considerations for Use of COVID-19 Vaccines](#) for details. Schedule is subject to change.

California COVID-19 Vaccination Program IMM-1396 (7/20/22) Page 2 of 3

COVID-19 Vaccine Timing–Adolescent/Adult

Vaccinate ALL 58

Schedule if Moderately or Severely Immunocompromised

Age	Vaccine	Primary Doses	Booster Doses
12-17	Moderna–Adol/Adult	1st Dose → 4 weeks → 2nd Dose → ≥4 weeks → 3rd Dose	
12+	Pfizer/Adol/Adult	1st Dose → 3 weeks → 2nd Dose → ≥4 weeks → 3rd Dose	≥3 months → 1st Booster (Ages 12-17: Pfizer) ≥4 months → 2nd Booster (Ages 12-17: Pfizer)
18+	Moderna–Adol/Adult	1st Dose → 4 weeks → 2nd Dose → ≥4 weeks → 3rd Dose	≥3 months → 1st Booster (Ages 12-17: Pfizer) ≥4 months → 2nd Booster (Ages 12-17: Pfizer)
18+	Janssen (J&J) Pfizer/Moderna preferred*	1st Dose → 4 weeks → 2nd Dose of Moderna/ Pfizer	≥2 months → 1st Booster (Ages 12-17: Pfizer) ≥4 months → 2nd Booster (Ages 12-17: Pfizer)
18+	Novavax	1st Dose → 3 weeks → 2nd Dose	

* Although use of mRNA COVID-19 vaccines is preferred, the Janssen vaccine may be offered in [some situations](#).
 View [Interim Clinical Considerations for Use of COVID-19 Vaccines](#) for details. Schedule is subject to change.

California COVID-19 Vaccination Program IMM-1396 (7/20/22) Page 3 of 3

Novavax Storage and Handling

Kate McHugh, CDPH

Receiving Shipments

- Vaccine ships like other routine refrigerated vaccines at temperatures between 2° to 8°C (36° to 46°F)
- Refer to the COVID-19 Provider Operations Manual's [Novavax Fact Sheet](#) for storage & handling details and receiving instructions





Receiving & Storing Vaccines

Novavax Vaccine 18Y+ Fact Sheet

Product (COVID-19 Vaccine, Adjuvanted) is authorized under EUA as a two-dose primary series for individuals 18 years and older. **DO NOT DILUTE.**

Vaccine contains SARS-CoV-2 spike protein and Matrix-M adjuvant; adjuvants are added to enhance the immune response of the vaccinated individual ([read more](#)).

Product Profile: NDC 80631-0100-01 [Fact Sheet for HCPs](#) | [Recipients](#)

-  Vaccine ships like other routine refrigerated vaccines at temperatures between 2° to 8°C (36° to 46°F).
-  Vaccine ships in a small, single-use shipper; dispose of shipper; do NOT use shipper for vaccine storage. Ancillary kit ships separately.
-  Store unpunctured multi-dose vials in a refrigerator between 2° to 8°C (36° to 46°F) **until expiration**. Protect from light. **DO NOT FREEZE.**
-  **Organize storage units** to reduce administration errors; group products by age and label cartons, baskets, or shelf space in large letters.
- Apply [storage and handling labels](#) to cartons or plastic bag holding vials to prevent administration errors.
- Read the vial label carefully to avoid administration errors.
- Hold punctured vials between 2° to 25°C (36° to 77°F) for up to **6 hours** then discard.
- No expiration date is printed on the vial or carton; to find expiration date, go to [novavaxcovidvaccine.com](#). Check with manufacturer or CDC's [COVID-19 Vaccine Expiration Date Report](#) for expiration dates and extensions; write expiration date on carton.
- Do not use vaccine after the expiration date or beyond-use date.**
- [Preparation & Administration Summary](#) | [Storage & Handling Summary](#) | [Standing Orders](#)

08/11/22 67

Receiving & Storing Novavax Vaccine

Receiving & Storing Novavax Vaccine

California COVID-19 Vaccination Program



Upon delivery, sites assume responsibility for storing vaccines in temperature-controlled environments. Never reject vaccine shipments.

Novavax COVID-19 Vaccine, Adjuvanted | [Fact Sheet](#)

- Product (Vial NDC 80631-100-01) is available in 100-dose carton; adult ancillary kit ships within 24-48 hours of vaccine and includes PPE.
- Authorized under EUA as a **2-dose primary series** for ages 18Y+. Do not dilute.
- Vaccine contains SARS-CoV-2 spike protein and Matrix-M adjuvant; adjuvants are incorporated into some vaccines to enhance the immune response of the vaccinated individual ([read more](#)).
- Distribute [Fact Sheet for Recipients & Caregivers](#) prior to vaccination.
- Vaccine ships like other routine refrigerated temperatures between 2° to 8°C (36° to 46°F).
- Store unpunctured multi-dose vials in a refrigerator between 2° to 8°C (36° to 46°F) **until expiration**. Protect from light. **DO NOT FREEZE**.
- Hold punctured vials between 2° to 25°C (36° to 77°F) for up to **6 hours** then discard.
- Apply [storage and handling labels](#) to cartons to prevent administration and handling errors.
- Dispose of cooler and packing materials; there is no return option available for refrigerated shippers.
- CDC's Preparation & Administration Summary ([TBD](#)), [Storage & Handling Summary](#), and [Standing Orders](#).
- See CDC [COVID-19 Vaccine Product Guide](#) (details about vaccine, kits, dimensions, PPE & needles; to be updated for Novavax) or [CDPH chart](#).

Vaccine Expiration Dates

No expiration date is printed on vial or carton. To find expiration date by lot number, [check online](#). Do not use vaccine after the expiration.

Do not dispose of vaccine without ensuring the expiration date has passed. As expiration dates draw near, check with the manufacturer for any extensions, or use CDC's [COVID-19 Vaccine Lot Number and Expiration Date Report](#). (This site requires you to [register](#) before accessing the information.) As expiration dates are extended, use CDC's [expiration date tracker](#) to record updated expiration dates.

Critical Notifications

Coordinators receive emails regarding order confirmations, advance shipment notices of vaccine and kits, and temperature monitoring alerts. Add [critical senders](#) to your contact list, or work with IT staff to have these senders added to your organization's email whitelist, to ensure emails are not filtered to Spam or Junk folders.

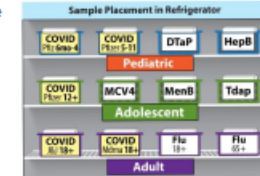
California COVID-19 Vaccination Program

IMM-1436 (7/25/22)

Organizing Storage Units to Reduce Errors

Set up storage units so staff can locate the correct vaccine to reduce errors caused by inadvertent administration of products similar in packaging or close in age indicators. Ensure vaccinators can easily locate correct product:

- Group vaccines by age (pediatric, adolescent, adult).
- Label cartons, baskets, or shelf space in large letters.
- Store vaccines and diluents together if storage requirements are the same. Never freeze diluent.
- Store other medicines and biologics on separate shelves.



Instructions

Follow these instructions to receive and store Novavax vaccine.

Step	Description
1.	Examine shipper for signs of physical damage.
2.	Open cooler and remove WarmMark monitor (may be located under frozen gel packs at top of cooler).
3.	Remove instruction card for temperature monitor and follow guidance on back to read the monitor. <ul style="list-style-type: none"> • If temperatures are too warm, report as a shipment incident.
4.	Inspect vaccine carton for damage, confirm order quantities, and confirm there is no expired vaccine. <ul style="list-style-type: none"> • Report any discrepancies or expired vaccine as a shipment incident.
5.	If vaccine is ready to use, transfer vial trays to your refrigerator, vials upright and in original packaging to protect from light. <ul style="list-style-type: none"> • Store between 2°C and 8°C (36°F and 46°F) until expiration. Do not freeze. • Apply storage and handling labels to cartons to prevent administration and handling errors.
6.	Report shipment incidents in myCAvax for vaccine product or kits (including temperature excursions in transit, damage, or order discrepancies) the same day the shipment arrived.
7.	Dispose of cooler and packing materials. Do not return shipper to McKesson.

California COVID-19 Vaccination Program

IMM-1436 (7/25/22)

Long Term Storage and Beyond Use Times

- Do not freeze!
- Store the unpunctured vial in a refrigerator between 2° to 8°C (36° to 46°F) until published expiration date
 - Vials do not have expiration dates printed on them
 - Expiration checker: novavaxcovidvaccine.com
 - Protect vials from light during storage
- After the first needle puncture, hold the vial between 2° to 25°C (36° to 77°F) for up to 6 hours
 - Discard the vial 6 hours after the first puncture

Novavax Ordering

Christina Sapad, CDPH

Novavax Orders

- Minimum standard order – 100 doses
- Adult ancillary kit ships within 24-48 hours of vaccine, but can be opted-out
- Vaccines are distributed through McKesson and follow the same [distribution cadence](#) as Moderna and J&J vaccine
- If your LHJ is participating in local fulfillment of small orders, orders of less than 100 doses can be submitted.
- CDPH is currently working with our Third-Party Redistributor (TPR), AmerisourceBergen, on enabling small orders for Novavax (min 30 doses, max 90 doses)
 - Timeline: Available for TPR small orders the week of 8/22, for shipments to begin the following week

My Turn

Eric Norton, My Turn

My Turn Novavax Update

*50 appointments per CSV



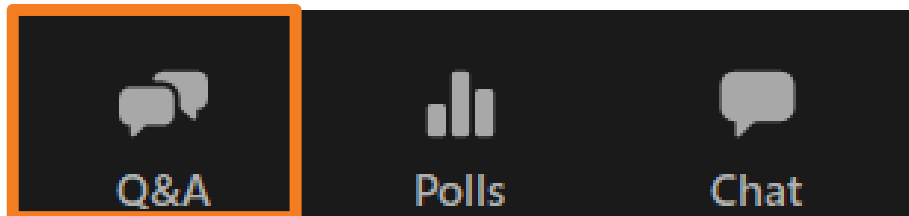
The My Turn team is prioritizing the launch of My Turn outbreaks to ensure the Monkeypox functionality is in the upcoming release. We expect Novavax to be available in My Turn starting in late August.

In the interim, clinics can capture Novavax vaccination data offline using a bulk upload CSV file which is available on EZIZ under the [My Turn Offline Resources](#) section. You can use this file to easily upload the appointments once Novavax becomes available in My Turn.

You may contact the My Turn Help Desk by calling 833-502-1245, Option 4, or emailing MyTurn.Clinic.HD@accenture.com for any additional questions.

Questions?

During today's session, please use the Q&A panel to ask your questions so CDPH subject matter experts can respond directly.



Wrap-up

Leslie Amani, CDPH

Additional Support

Type of Support

Description

Updated 6.6.22



COVID-19 Provider Call Center

The COVID-19 Call Center for Providers and Local Health Departments is dedicated to medical providers in California and their COVID-19 response, specifically addressing questions about State program requirements, enrollment, and vaccine distribution, including the Vaccine Marketplace.

- Email: covidcallcenter@cdph.ca.gov
- Phone: (833) 502-1245, Monday through Friday from 8AM–6PM



Enrollment Support

For Provider enrollment support, please contact myCAvax Clinic Operations at

- Email: myCAvaxinfo@cdph.ca.gov



myCAvax Help Desk

Dedicated staff provide up-to-date information and technical support on the myCAvax system.

- Email: myCAvax.HD@Accenture.com
- Phone: (833)-502-1245, option 3, Monday through Friday 8AM–6PM

For training opportunities: <https://eziz.org/covid/education/>



My Turn Clinic Help Desk

For **onboarding support** (those in the process of onboarding): myturnonboarding@cdph.ca.gov
For **technical support** with My Turn Clinic for COVID-19 and flu vaccines: MyTurn.Clinic.HD@Accenture.com or (833) 502-1245, option 4: Monday through Friday 8AM–6PM

For job aids, demos, and training opportunities: flu at <https://eziz.org/covid/myturn/flu/> and COVID at <https://eziz.org/covid/myturn/>



Archived Communications

For archived communications from the COVID-19 Provider Call Center about the California COVID-19 Vaccination Program visit

- Website: [EZIZ Archived Communications](#)



Thank you!



Monday

Provider Therapeutics Webinar

Next session: Monday August 15, 12PM

My Turn and myCAvax Office Hours

Next session: Monday, August 22, 12PM

Friday

Provider Office Hours

Next session: Friday, August 19, 9AM