State of California—Health and Human Services Agency
California Department of Public Health

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TO: California Providers of COVID-19 Vaccination Services

FROM: Robert Schechter, M.D., Chief
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SUBJECT: Novavax COVID-19 Vaccine, Adjuvanted, Interim Information

HIGHLIGHTS

- Novavax COVID-19 Vaccine is an option for persons 12 years and older as a two-dose primary series, administered 3-8 weeks apart (CDPH COVID-19 Vaccine Timing).
- Novavax COVID-19 Vaccine is supplied in multiple-dose vials.
- Under initial standards, unopened vials may be stored at 2°C to 8°C (36°F to 46°F) until the published expiration date. **Do not freeze**.
- Expiration dates are not printed on the Novavax vial labels but can be determined at the Novavax Expiry Date Checker by entering the lot number of a specific vial.
- The information sheet about the v-safe smartphone safety monitoring system should be provided to patients who should be encouraged to participate.
- This letter is intended to provide information about the Novavax COVID-19 vaccine and provide links to CDC, CDPH, FDA, and other resources.

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SUMMARY

Novavax COVID-19 Vaccine has received federal Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for use in persons at least 12 years of age as a two-dose primary series. CDC has recommended its use as an initial immunization series against COVID-19.

BACKGROUND AND COMPOSITION

Vaccine components include:

- SARS-CoV-2 recombinant spike protein
- 50 mcg Matrix-M adjuvant, composed of Fraction-A and Fraction-C of saponin extracts from the soapbark tree, *Quillaja saponaria* Molina
- cholesterol
- phosphatidylcholine
- potassium dihydrogen phosphate
- potassium chloride
- disodium hydrogen phosphate dihydrate
- disodium hydrogen phosphate heptahydrate
- sodium dihydrogen phosphate monohydrate
- sodium chloride
- polysorbate 80

Each 0.5 mL dose of the Novavax COVID-19 Vaccine, Adjuvanted may contain residual amounts of baculovirus and Sf9 cell proteins (≤ 0.96 mcg), baculovirus and cellular DNA (≤ 0.00016 mcg), lentil lectin (< 0.025 mcg), methyl-α-D-mannopyranoside (2 mcg), pluronic F-68 (< 2.19 mcg), simethicone (<0.92 mcg), Triton X-100 (< 0.025 mcg), and Tergitol (NP9) (< 0.05 mcg). The pH is adjusted with sodium hydroxide or hydrochloric acid.

Novavax COVID-19 Vaccine does not contain a preservative. The vial stoppers are not made with natural rubber latex.

More information can be found in the Novavax Covid-19 Vaccine FDA Fact Sheets and CDC Novavax COVID-19, Adjuvanted Vaccine: Overview and Safety.

ACIP RECOMMENDATIONS FOR VACCINE USE

Eligible Groups

Novavax COVID-19 Vaccine can be given to persons 12 years and older as a primary series, and currently is not authorized for booster doses. Recent ACIP meeting materials may be referenced here. Current COVID-19 vaccine recommendations by ACIP and CDC may be found at COVID-19 ACIP Vaccine Recommendations, the Interim Recommendations of the ACIP for Use in Persons Aged ≥18 years, and CDC Interim Clinical Considerations.

Minimum Ages and Intervals

- Minimum age for any dose: 12 years
- Minimum interval between dose 1 and 2: 21 days

For reference, please see the CDPH COVID-19 Vaccine Timing job aid.

Contraindications and Precautions
Do not administer Novavax COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Novavax COVID-19 Vaccine or a known diagnosed allergy to any component of the Novavax COVID-19 Vaccine, including to polysorbate. Vaccine components are listed on the FDA fact sheets. Any allergy-related contraindication to one type of Covid-19 vaccine is a precaution to other types.

CDC considers a history of an immediate allergic reaction to any vaccine other than COVID-19 vaccine or to any injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"]) to be a precaution but not a contraindication to vaccination. Additional clinical considerations and information on contraindications and precautions can be found in the CDC Interim Clinical Considerations.

Administration with Other Vaccines
COVID-19 vaccines may be administered without regard to timing of other vaccines, including on the same day as other vaccines, with the following exception: If an orthopoxvirus vaccine is administered first, consider waiting 4 weeks before administering the Moderna, Pfizer, or Novavax COVID-19 vaccine. If a COVID-19 vaccine is administered first, no minimum interval is necessary before receiving orthopoxvirus vaccination for prophylaxis in the setting of an outbreak.

If multiple vaccines are administered at a single visit, administer each injection in a different injection site. The deltoid may be used for multiple injections in adults.

Best practices for multiple injections include:

- Label each syringe with the name and the dosage (amount) of the vaccine, lot number, the initials of the preparer, and the exact beyond-use time, if applicable.
- Separate injection sites by 1 inch or more, if possible.
- Administer the COVID-19 vaccines and vaccines that may be more likely to cause a local reaction in different limbs, if possible.

See general best practices and The Epidemiology and Prevention of Vaccine-Preventable Diseases: "The Pink Book" for further information.

DOSAGE AND ADMINISTRATION

Each dose contains 5 micrograms SARS-CoV-2 recombinant spike protein and 50 micrograms of Matrix-M adjuvant.

Storage and Handling Protect from light. **Do not freeze vials.**

	Viability
Unpunctured vial: Refrigerator (2°C to 8°C)	Until Published Expiration Date
Post puncture: 2° to 25°C	6 hours

Expiration dates are not printed on the Novavax vial labels but can be determined at the Novavax Expiry Date Checker by entering the lot number of a specific vial.

For reference, please refer to the CDPH Covid-19 Vaccine Product Guide and Storage and Handling of Novavax Covid-19 Vaccines.

REACTOGENICITY AND ADVERSE EVENTS

Adverse reactions reported in clinical trials following administration of the Novavax COVID-19 Vaccine, Adjuvanted include injection site pain/tenderness, fatigue/malaise, muscle pain, headache, joint pain, nausea/vomiting, injection site redness or swelling, fever, chills, injection site pruritus, hypersensitivity reactions, lymphadenopathy-related reactions, myocarditis, and pericarditis. Materials presented at ACIP meetings regarding safety and immunogenicity data can be found at the ACIP presentation slides website.

Before vaccination, providers should counsel COVID-19 vaccine recipients about expected local (e.g., pain, swelling, erythema at the injection site) and systemic (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) post-vaccination reactions.

Antipyretic or analgesic medications can be taken for the treatment of post-vaccination local or systemic symptoms; these medications should not be used prophylactically for the purposes of prevention of post-vaccination symptoms.

Anaphylactic reactions have been rarely reported following receipt of COVID-19 vaccines. Administration of antihistamines before COVID-19 vaccination to prevent allergic reactions is not generally recommended. CDC recommends observation of all vaccine recipients for at least 15 minutes after vaccination, and up to 30 minutes for persons at higher risk of anaphylaxis. Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs. Further information can be found at Preparing for the Potential Management of Anaphylaxis and Lab Testing After Severe Allergic Reaction Following COVID-19 Vaccination.

Fainting (syncope) may occur in association with any injectable vaccine, especially in adolescents. Procedures should be in place to prevent falling injuries and manage syncopal reactions. People should be seated or lying down during vaccination and observed for 15 minutes after vaccination as noted above. If syncope develops, patients should be observed until symptoms resolve.

Cases of myocarditis and pericarditis were identified in clinical trials of Novavax COVID-19 Vaccine and have also been reported during post-authorization use outside of the United States, suggesting a potential increased risk for these conditions after receiving the Novavax COVID-19 vaccine. The rare risk of myocarditis might be reduced by a longer interval between the first and second dose. FDA has authorized and ACIP and CDC have recommended Novavax COVID-19 vaccines in adults 18 years and older based on the determination that the benefits of COVID-19 vaccination outweigh the risks.

Further information on Reactogenicity and Adverse Events can be found at the CDC Interim Clinical Considerations website under the headings:

- Patient Counseling
- Contraindications and Precautions
- Safety Considerations for Novavax COVID-19 Vaccine

VACCINE INFORMATION FACTSHEET

Prior to receiving Novavax COVID-19 Vaccine, provide the patient with a copy of the "Vaccine Information Fact Sheet for Recipients and Caregivers" and communicate the information in the Fact Sheet.

Documentation of vaccination

Provide a vaccination card to the patient that includes the date when the recipient needs to return for the next dose. Administration of each dose must be reported to the state or regional immunization registry.

To help monitor immunization safety, provide the v-safe information sheet to patients and encourage them to participate in v-safe. For more information, visit: www.cdc.gov/vsafe.

Reporting of vaccine adverse events

Adverse events that occur in a recipient following COVID-19 vaccination should be reported to VAERS. Vaccination providers are required by the FDA to report the following that occur after COVID-19 vaccination under BLA or EUA:

- Vaccine administration errors
- Serious adverse events
- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death

Reporting is encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967.

Additional CDC guidance on preventing, reporting, and managing administration errors can be found at the CDC Interim Clinical Considerations website.

ORDERING AND BILLING

Order Novavax COVID-19 Vaccine via your provider myCAvax account.

Billing Information for Vaccine

COVID-19 vaccines have been purchased by the federal Government for all people in the US, regardless of insurance or immigration status, at no cost to recipients. Vaccination providers are only able to be reimbursed for administering the vaccine. They may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine

administration fees for the vaccine recipient. However, there should be no patient cost sharing, or out-of-pocket cost, for all payor types for vaccine administration regardless of whether or not the vaccinator is in the payor's provider network. Providers may not charge an office visit or other fee if COVID-19 vaccination is the sole medical service provided, nor require additional medical services to receive COVID-19 vaccination.

The California Medical Association has provided a clear guide on reimbursement.

Medi-Cal Fee-For-Service and Medi-Cal Managed Care

The Department of Health Care Services is reimbursing the COVID-19 vaccine administration reimbursement under its fee-for-service (FFS) system. To avoid delays and denials in payment, physicians will need to submit claims for COVID-19 vaccine administration to Medi-Cal FFS rather than Medi-Cal managed care plans.

- CLAIM SUBMISSION – Medi-Cal FFS and Medi-Cal managed care claims should be submitted directly to Medi-Cal FFS with the patient's Medi-Cal FFS Benefit Identification Card (BIC) ID number rather than the managed care plan ID number.
- BILLING – Because vaccine has been purchased by the federal government, claims should include vaccine administration CPT codes only. Physicians should not charge for the vaccine itself.
- REIMBURSEMENT RATE (ADMINISTRATION) – $40 for each dose approved. For vaccine only encounters, FQHCs, RHCs, and Tribal RHCs will be reimbursed at $67/shot retroactive to November 2, 2020.

RESOURCES

- FDA EUA Fact Sheets for Novavax COVID-19 Vaccine, Adjuvanted
- EZIZ COVID-19 Resources: Updated information on vaccine management, administration, and more.
- CDC Novavax COVID-19 Vaccine: Includes job aids for vaccine preparation, storage and handling, administration, transport guidance, and more.
- CDC Interim Clinical Considerations for Use of COVID-19 Vaccines
- AAP vaccine recommendations and other information are available to AAP members at www.cispimmunize.org/.
- Vaccine Adverse Event Reporting System (VAERS), 1-800-822-7967.
- Vaccine Injury Compensation Program (VICP), which covers Novavax COVID-19 Vaccine.
- Additional information on vaccines can be found at http:/www.cdc.gov/vaccines/.