Immunization Branch Updates

7/27/22

Novavax COVID-19 Vaccine Updates

7/13/2022:

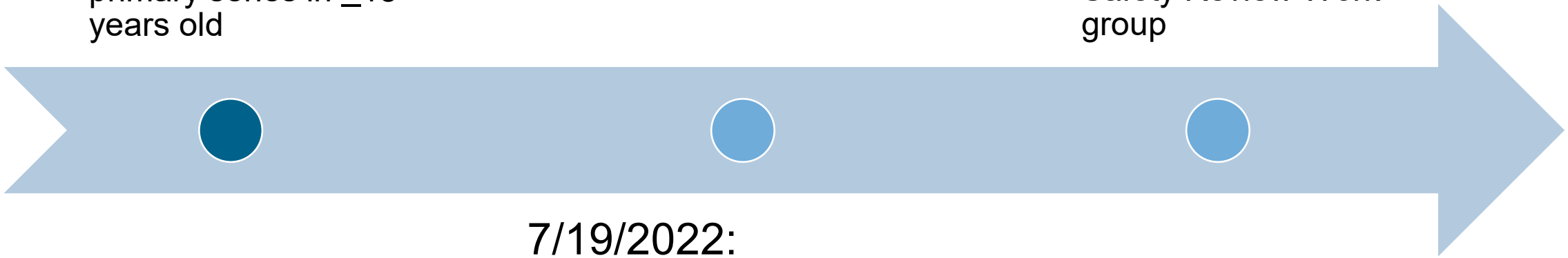
- FDA Authorized Emergency Use of Novavax COVID-19 Vaccine as a 2-dose primary series in ≥18 years old

7/19/2022:

- ACIP and CDC recommend Novavax for adults

7/22/2022:

- Approval by Western States Scientific Safety Review Work group



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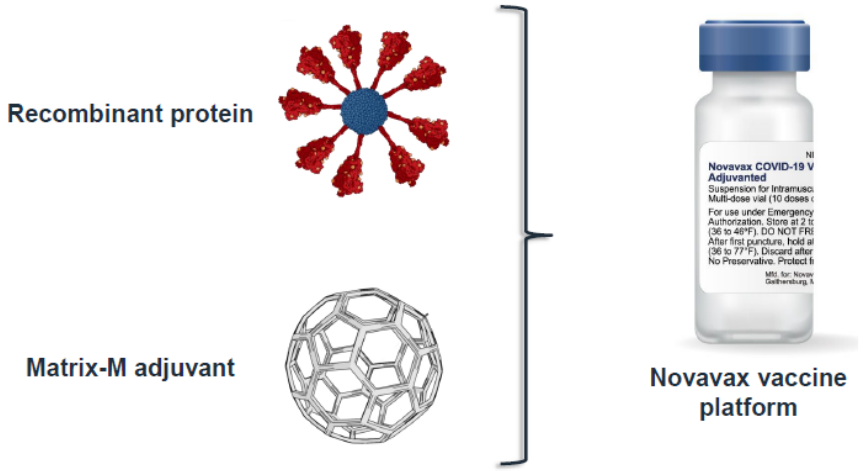
FDA Authorizes Emergency Use of Novavax COVID-19 Vaccine | ACIP Presentation Slides: July 19, 2022 | CDC Recommends Novavax for Adults | Western States Statement on Novavax COVID-19 Vaccine for Adults

Novavax COVID-19 Vaccine (NVX-Co2373)



- Novavax (NVX-Co2373) contains the SARS-CoV-2 recombinant spike protein and Matrix-M adjuvant.
  - Other protein subunit vaccines include hepatitis B, influenza, and pertussis (whooping cough) vaccines.
  - Other vaccines with adjuvants include tetanus and shingles vaccines.
- Granted Emergency Use Listing (EUL) by the WHO in December 2021
  - Authorized in 40+ countries,
  - Over 1 million doses given worldwide per Novavax

World Health Organization Emergency Use Listing of NVX-CoV2373
Covid-19 Vaccine Tracker-Novavax

Novavax Clinical Trial Data

- Phase III randomized controlled trial in adults 18 and older in the United States and Mexico
- Study enrollment and follow up occurred between December 2020-September 2021
  - Conducted during Alpha variant predominance
- The per protocol set included 17,272 participants in the vaccine groups and 8,385 in the placebo group

Outcome 1: Symptomatic Lab-confirmed COVID-19 Studies with Unvaccinated Comparator (n=1)

Population	Events/Vaccine[a] (n/N)	Events/Placebo[a] (n/N)	Vaccine efficacy (95% CI)
Primary Outcome[b]			
Ages ≥18 years	17/17272	79/8385	89.6% (82.4%, 93.8%)
Ages 18–64 years	15/15228	75/7417	90.3% (83.1%, 94.4%)
Ages ≥65 years	2/2044	4/968	76.3% (-29.1%, 95.7%)
Any comorbidity[c] (18–64 years)	6/6957	38/3451	92.2% (81.5%, 96.7%)
Any comorbidity[c] (≥65 years)	1/1125	3/580	82.8% (-64.9%, 98.2%)

a. 19,963 and 9,982 persons were randomized to vaccine and placebo

b. Cases diagnosed ≥7 days post dose 2 among persons without evidence of prior SARS-CoV-2 infection

c. Comorbidities: obesity, chronic kidney disease, chronic lung disease, cardiovascular disease, diabetes mellitus type 2

Adverse Reactions

- Most frequently reported solicited local adverse events were tenderness and injection-site pain.
- Most common solicited systemic adverse events were headache, myalgia, fatigue, and malaise.
- Severe local reactions (grade ≥3) were infrequent.
- Frequency of serious adverse events were similar in groups receiving vaccine (1.0%) and placebo (1.1%).

Novavax COVID-19 Vaccine: Preparation and Administration

Age indication:
18 years and older

Dose: 5 mcg SARS-CoV-2rS
50 mcg Matrix-M™ adjuvant

Injection volume:
0.5 mL

Preparation:
Do not dilute

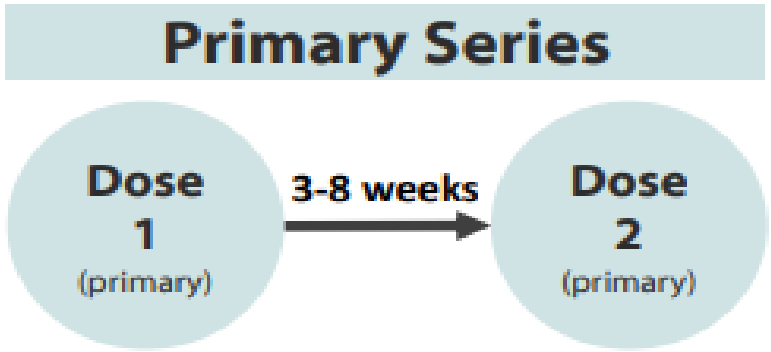
Doses per vial:
10 doses

Injection route/site:
Intramuscular/deltoid

Novavax Covid-19 Vaccine Schedule

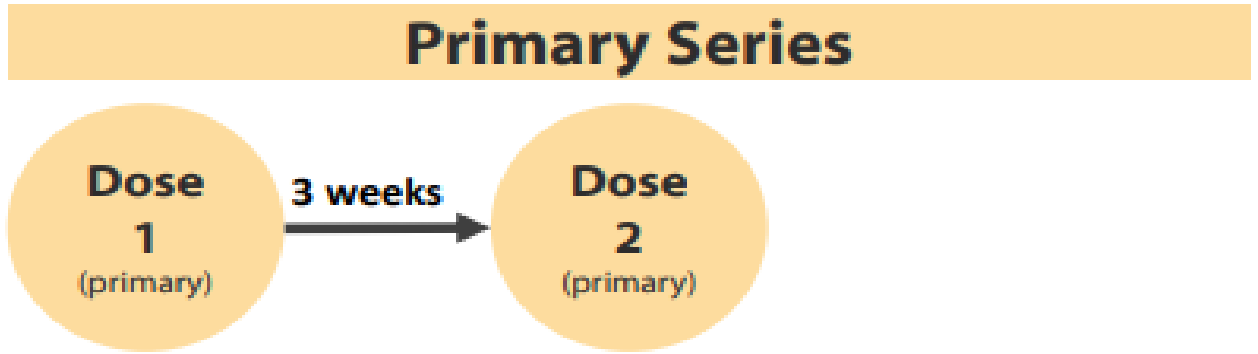
People who are **NOT** moderately or severely immunocompromised

Novavax
(18 years and older)



People who **ARE** moderately or severely immunocompromised

Novavax
(18 years and older)



Extended Interval Consideration

3-week interval	8-week interval

• People who are moderately or severely immunocompromised
• People ages 65 years and older
• When protection needs to be achieved soonest
  • High risk for severe disease
  • Living, working, or traveling to an area with high COVID-19 community levels
	• Reduced myocarditis risk
	  • Young adult males
	• Optimize vaccine effectiveness

Considerations for Extended Interval Between Dose 1 & 2

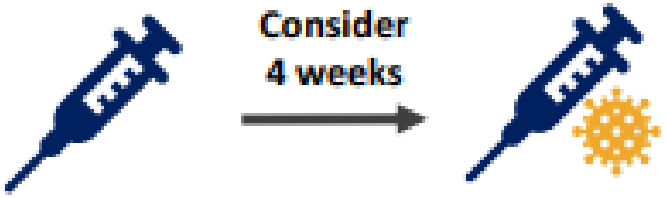
3-week interval	8-week interval
• People who are moderately or severely immunocompromised • People ages 65 years and older • When protection needs to be	• Reduced myocarditis risk • Young adult males • Optimize vaccine effectiveness

Coadministration

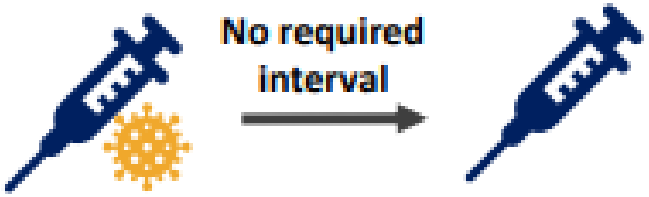
- In general, Covid-19 vaccines may be administered without regard to timing of other vaccines
- Routine administration of all age-appropriate doses of vaccines recommended for whom there are no contraindications
- Considerations:
  - If they are at risk of becoming behind on recommended vaccines
  - Risk of being infected with a vaccine-preventable disease
  - Risk for severe disease, if infected
  - Reactogenicity profile of vaccines

Coadministration: Orthopox Vaccine

If orthopoxvirus vaccine administered first: Might consider waiting 4 weeks before receiving a Moderna, Novavax, or Pfizer-BioNTech vaccine



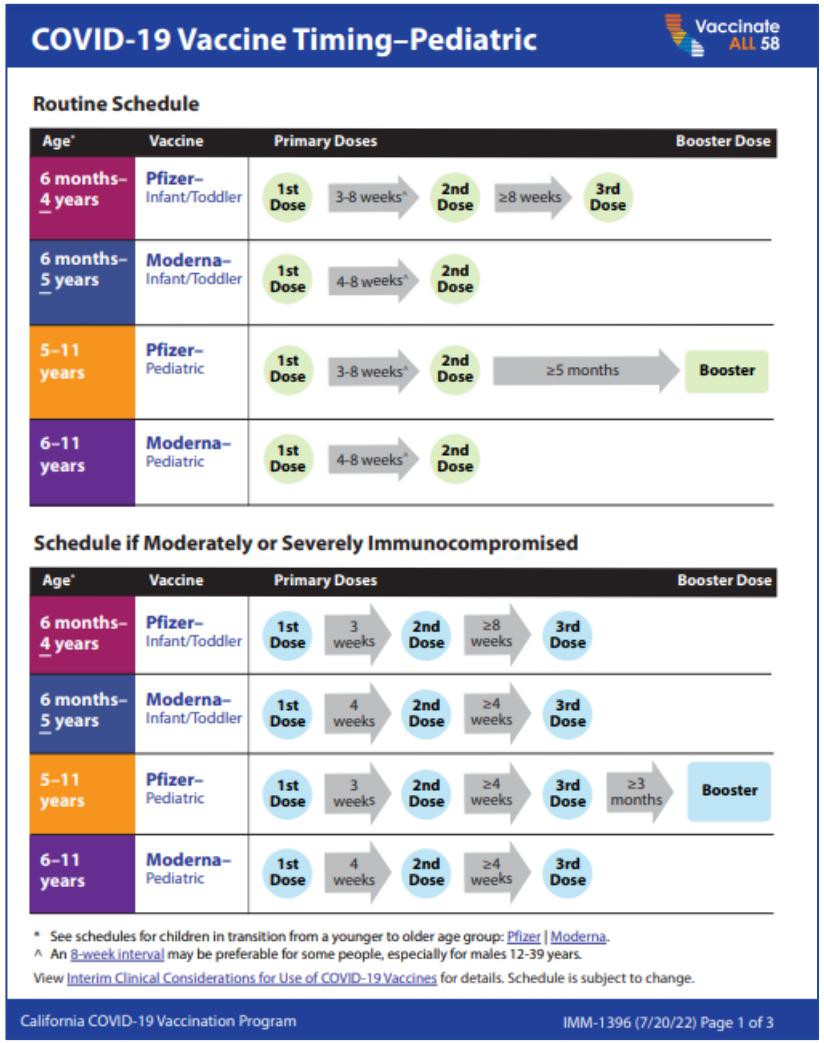
If Moderna, Novavax, or Pfizer-BioNTech administered first:
No minimum interval necessary before receiving orthopoxvirus vaccination for prophylaxis in the setting of an outbreak



Interim Clinical Considerations for Novavax COVID-19 Vaccine | ACIP Meeting, July 19, 2022

Updated with Novavax!

Vaccine Timing Guide: Pediatric/Adolescent/Adult



COVID-19 Vaccine Timing–Pediatric

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Routine Schedule

Age*	Vaccine	Primary Doses	Booster Dose
6 months–4 years	Pfizer–Infant/Toddler	1st Dose → 3-8 weeks^ → 2nd Dose → ≥8 weeks → 3rd Dose	
6 months–5 years	Moderna–Infant/Toddler	1st Dose → 4-8 weeks^ → 2nd Dose	
5–11 years	Pfizer–Pediatric	1st Dose → 3-8 weeks^ → 2nd Dose → ≥5 months	Booster
6–11 years	Moderna–Pediatric	1st Dose → 4-8 weeks^ → 2nd Dose	

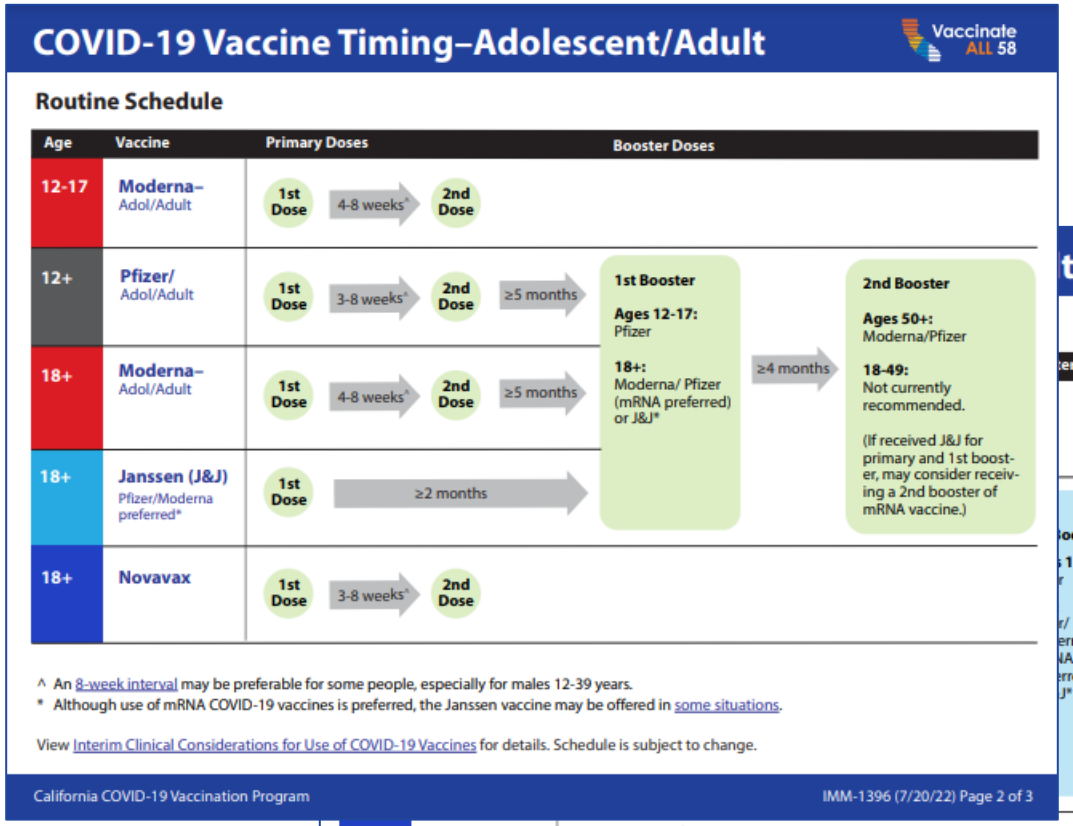
Schedule if Moderately or Severely Immunocompromised

Age*	Vaccine	Primary Doses	Booster Dose
6 months–4 years	Pfizer–Infant/Toddler	1st Dose → 3 weeks → 2nd Dose → ≥8 weeks → 3rd Dose	
6 months–5 years	Moderna–Infant/Toddler	1st Dose → 4 weeks → 2nd Dose → ≥4 weeks → 3rd Dose	
5–11 years	Pfizer–Pediatric	1st Dose → 3 weeks → 2nd Dose → ≥4 weeks → 3rd Dose → ≥3 months	Booster
6–11 years	Moderna–Pediatric	1st Dose → 4 weeks → 2nd Dose → ≥4 weeks → 3rd Dose	

* See schedules for children in transition from a younger to older age group: Pfizer | Moderna.
^ An 8-week interval may be preferable for some people, especially for males 12-39 years.

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 1 of 3



COVID-19 Vaccine Timing–Adolescent/Adult

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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; 18+: Moderna/ Pfizer (mRNA preferred) or J&J* → ≥4 months → 2nd Booster: Ages 50+: Moderna/Pfizer; 18-49: Not currently recommended. (If received J&J for primary and 1st booster, may consider receiving a 2nd booster of mRNA vaccine.)
18+	Moderna–Adol/Adult	1st Dose → 4-8 weeks^ → 2nd Dose → ≥5 months	
18+	Janssen (J&J) Pfizer/Moderna preferred*	1st Dose → ≥2 months	
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

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12-17:
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NA
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J*

≥4 months

2nd Booster
Ages 12-17: Pfizer
18+: Moderna/ 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.

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