

# Clinical Update

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# Updated Boosters Now Authorized for Children

- 10/12/22: FDA issued Emergency Use Authorization (EUA) for updated (bivalent) booster for pediatric populations:
  - [Pfizer FDA fact sheet for HCP](#): 5-11 years - 0.2ml dose
  - [Moderna FDA fact sheet for HCP](#): 6-11 years - 0.25 ml dose; 12+ years - 0.5 ml dose
- CDC has updated their COVID-19 vaccine guidelines to include [pediatric updated booster recommendations](#)
- Western States Scientific Safety Review Workgroup (WSSSRW) [released a statement](#) aligning with CDC's updated booster guidelines.

# Updated Boosters

- People ages 5 years and older are recommended to receive **1 age-appropriate bivalent mRNA booster dose** after completion of any FDA-approved or FDA-authorized monovalent primary series or previously received monovalent booster dose(s).
- **This new booster recommendation replaces all prior booster recommendations for this age group**
- Monovalent mRNA vaccines are no longer authorized as a booster dose for people ages 5 years and older.

# Updated Boosters

- Can be administered at least 2 months after either completion of the primary series or last monovalent booster dose
- Any homologous or heterologous bivalent mRNA vaccine can be used if a booster dose is FDA-authorized for use in that age group.
- J&J vaccine remains available as first booster for certains people

# COVID-19 and Flu Vaccine Coadministration

- Routine administration of all age-appropriate doses of vaccines simultaneously is recommended for persons for whom no specific contraindications exist.
- COVID-19 vaccines may be administered regardless of timing of influenza vaccines, including simultaneous administration of COVID-19 and influenza vaccines on the same day.
  - Administer each vaccine in a different injection site (at least 1 inch apart)
  - Administer vaccines that may be more likely to cause a local reaction (e.g., tetanus-toxoid-containing and PCV13, adjuvanted or high-dose influenza) in different limbs, if possible.

# Vaccination After Covid-19 Infection

- People with known current SARS-CoV-2 infection should defer any COVID-19 vaccination, including booster vaccination, at least until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met
- In addition, people who recently had SARS-CoV-2 infection may consider delaying a primary series dose or booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic).

# Novavax Monovalent Booster Authorized and Recommended for Some Adults

- 10/19/22: CDC's Director Dr. Rochelle Walensky signed a decision memo and released a [media statement](#) allowing Novavax monovalent COVID-19 boosters for people ages 18 years and older targeting the original COVID-19 strain, following FDA's granting of [emergency use authorization](#).
- Adults who completed primary vaccination using any COVID-19 vaccine **and have not received any previous booster dose(s)** may receive a monovalent Novavax booster dose **at least 6 months after completion of the primary series** if they are unable to receive or unwilling to receive an mRNA vaccine and would otherwise not receive a booster dose.

# Novavax Vaccine Fact Sheet

## Fact Sheet for Healthcare Providers

## Fact Sheets for Recipients and Caregivers

## Set-up Storage Unit and Data Logger

## Novavax Storage and Handling Labels

## Novavax COVID-19 Webpage

### Novavax Vaccine Fact Sheet

Product (COVID-19 Vaccine, Adjuvanted) is authorized under EUA as a two-dose primary series for ages 12Y+ and as a **first** booster for ages 18Y+ for whom a bivalent booster is not accessible or clinically appropriate and who elect to receive Novavax vaccine because they would otherwise not receive a booster dose ([read more](#)). **DON'T 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). For receiving, see [How to Receive Novavax Vaccine](#).
- 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.



- To avoid errors, read label carefully; don't rely on cap color.
- Dosing volume 0.5 mL (5 mcg) for primary series and **first** booster dose ([read more](#)). Do not pool excess vaccine from multiple vials.
- 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.**
- *From CDC: [Preparation & Administration Summary](#) | [Storage & Handling Summary](#) | [Standing Orders](#). From CDPH: [Risks & Benefits \(Spanish\)](#)<sup>68</sup>*

10/20/2022



# Vaccine for Children (VFC) Program

- Once COVID-19 vaccines are commercialized and no longer available under the National COVID-19 Response, VFC providers will be able to order the vaccines through the VFC program.
- The timeline for commercialization of COVID-19 vaccines in the US has not yet been finalized.
- The VFC program is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay.
- The addition of a vaccine to the VFC program **does not** mean that the vaccine is or will be required by states for school entry.

# Updated Immunization Schedule

- CDC's Advisory Committee on Immunization Practices (ACIP) recommended the addition of Covid-19 vaccines to the 2023 childhood and adult [immunization schedules](#)
- Updated schedules and program guidance will be published in early 2023
- School-entry vaccination requirements are determined by state or local jurisdictions