COVID-19 Vaccine Updates: 2023-2024 Products and Recommendations

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Authorization Updates

- The FDA authorized and ACIP recommends updated, 2023-2024 mRNA COVID-19 vaccines for use in individuals 6 months and older.
- FDA has not authorized or approved an updated Novavax vaccine for 2023-24. Existing Novavax may still be administered at this time if it is determined that the individual should not wait for the 2023-2024 Novavax COVID-19 vaccine.
- Bivalent mRNA COVID-19 vaccines are no longer authorized for use in the United States.



Remove all Bivalent Pfizer & Moderna Vaccines from Inventory

Discard bivalent inventory

- Spoiled, wasted or expired COVID-19 vaccines may not be returned.
- Dispose as medical waste according to your organization's policy.
- CDC asks that clinics also destroy packaging to decrease the possibility of counterfeiting.

Report wasted bivalent inventory

Deduct wasted doses from each site's inventory in ALERT IIS using the reason "Other, not usable-reported by provider."

Tip Sheet on How to Manually Adjust Inventory in ALERT IIS



Is administration of a bivalent mRNA vaccine a vaccine error?

Yes.

The CDC considers this an error as soon as the bivalent vaccines were no longer authorized by the FDA (no grace period).

For efficiency, if this same error occurred multiple times (e.g., a clinic vaccinated with bivalent all day and didn't see the new authorization until the next day), providers can submit a single batch report.

To make a VAERS report, visit: <u>https://vaers.hhs.gov/</u>

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ACIP Discussion on the Benefits of COVID-19 Vaccines

- Updated COVID-19 vaccines provides protection against the currently circulating variants.
- Last year's updated vaccine was effective at preventing COVID-19 related hospitalizations and death.
- Accumulating evidence that COVID-19 vaccination reduces Post-COVID-19 conditions (Long COVID) among both children and adults.
- COVID-19 vaccines have a high degree of safety.
- Benefits outweigh risks in all age groups.



Moderna: 2023-2024 COVID-19 Vaccines

Product	COVID-19 Vaccine Vaccine single dose vial	Spikevax single dose vial	Spikevax single dose pre-filled syringe		
Age Group	6 months - 11 yrs	yrs 12 yrs and older			
Vial colors	Cap: Dark blue Label: Green	Cap: Dark blue Label: Dark blue	Cap: N/A Label: Dark blue		
Dosage	25 µg	50 µg	50 µg		
Injection volume	0.25 mL	0.5 mL	0.5 mL		
Dilution required	No	No	No		
Storage & Handling	Standard freezer (-50° to -15° C) until expiration date. Refrigerator (2° to 8° C) for up to 30 days. Room temperature up to 24 hrs. Protect from light. Do not refreeze.				
_	Thaw vials in refrigerator for 45 mins or at room temp. for 15 mins.		Thaw pre-filled syringes in refrigerator for 1 hr or at room temp. for 45 mins.		

Pfizer: 2023-2024 COVID-19 Vaccines

Product	COVID-19 Vaccine multidose vial (3 doses after dilution)	COVID-19 Vaccine single dose vial	Comirnaty single dose vial	Comirnaty single dose pre-filled syringe	
Age Group	6 months - 4 yrs	5 – 11 yrs	12 yrs & older		
Vial colors	Cap: Yellow Label: Yellow	Cap: Blue Label: Blue	Cap: Gray Label: Gray	Cap: N/A Label: Gray	
Dosage	3 µg	10 µg	30 µg		
Injection volume	0.3 mL	0.3 mL	0.3 mL		
Dilution required	Yes (1.1 mL)	No	No		
Storage & Handling	 Ultracold freezer (-90° to -60° C) until expiration date. Refrigerate (2° to 8° C) up to 10 weeks. May be stored at room temperature up to 12 hours. Discard any remaining vaccine after 12 hours.* Protect from light. Do not refreeze. *For prefilled syringes: After removing tip cap and attaching needle, vaccine should be administered immediately. If it cannot be used immediately, it must be used within 4 hours. 				

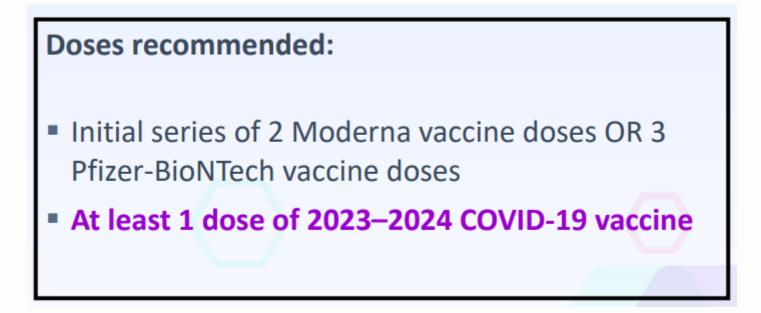
Overview of Recommendations

ACIP recommends that everyone 6 months and older receive at least one dose of the updated 2023-2024 COVID-19 vaccine to be up to date.

- **One dose** for ≥5 years (including ≥65 years)
- Additional doses may be recommended for:
 - Children 6 months through 4 years
 - People with moderate or severe immunocompromise may receive additional doses at their health care provider's discretion



Updated Recommendations: 6 months-4 years





Updated Recommendations: 5 years and older

Doses recommended:

 1 dose of 2023–2024 COVID-19 vaccine, regardless of prior vaccination history



Updated Recommendations Moderately or severely immunocompromised

Doses recommended:

- Initial COVID-19 vaccine series
- At least 1 2023–2024 COVID-19 vaccine dose
- May receive 1 or more additional 2023-2024 mRNA COVID-19 vaccine doses



Coadministration of COVID-19 and Other Vaccines

- Simultaneous administration is recommended if there are no contraindications.
- Eligible patients may receive COVID-19, influenza, and respiratory syncytial virus (RSV) vaccines at the same visit.
- For children ≥6 months of age, simultaneous administration of COVID-19 vaccine and nirsevimab is recommended.

Note: There are additional considerations if administering mpox and COVID-19 vaccines.

From ACIP Meeting, 9/12/23: <u>https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-09-12/11-COVID-Wallace-508.pdf</u>. Additional information in the <u>Health Alert Network (HAN), 9/5/23</u>.



Additional Help for Providers

- CDC's <u>Interim Clinical Considerations</u> for the Use of Authorized COVID-19 Vaccines has been updated.
- Oregon's <u>COVID-19 Immunization Protocol</u> has been updated and posted.
- Upcoming COCA Call, September 19, 11-Noon (PST)
 Webinar link: Preparing for the Upcoming Respiratory Virus Season: <u>Recommendations for Influenza, COVID-19, and RSV Vaccines in Older</u> <u>Adults</u>
- Coding:
 - OHA's CPT, NDC and CVX charts
 - CDC's <u>Respiratory Season Code Set</u> (CPT & NDC)
 - Eligibility coding for Bridge Access Program Vaccines: Use "O" for Other state-supplied.



Manufacturer Trainings & Resources

• Pfizer

– Trainings

Visit Pfizer Medical Affairs Webinars for days and times.

- Resources
 - <u>Pfizer Formulation/ Presentation Guide</u>
 - Fact Sheet: Pfizer COVID-19 Vaccines, 6 months-11 yrs (EUA)
 - Fact Sheet Translations: Pfizer COVID-19 Vaccines, 6 months-11 yrs (EUA)

Moderna

- Trainings
 - Tuesday, 9/19 at 9 am In-depth Panel Discussion, 45 min.
 - Visit <u>Moderna Medical Team Briefings</u> for days and times, 15 min. presentations followed by Q & A

– Resources

- Dear Healthcare Provider Letter
- Fact Sheet: Moderna COVID-19 Vaccines 6 months -11 yrs (EUA)
- Fact Sheet Translations: Moderna COVID-19 Vaccines, 6 months-11 yrs (EUA)



Questions?

OIP Help Desk VFC.Help@odhsoha.oregon.gov (800) 980-9431

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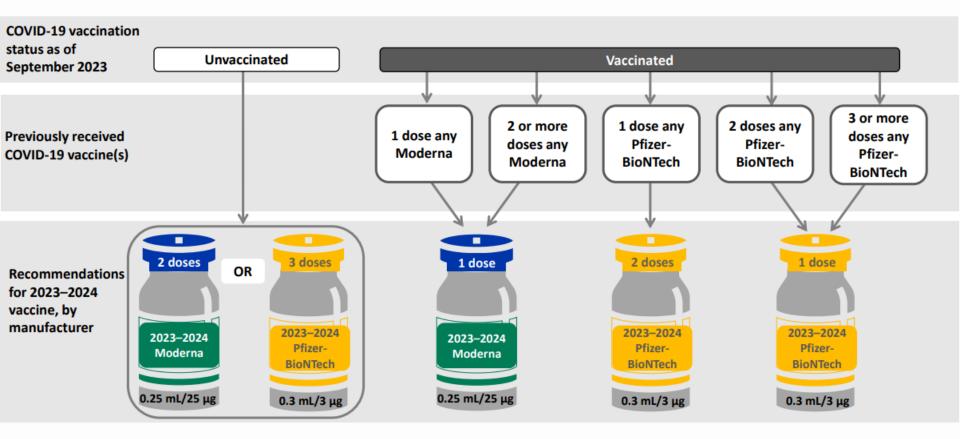


Updated 2023-2024 COVID-19 Vaccine Flowcharts

From ACIP Meeting, 9/12/23: https://www.cdc.gov/vaccines/acip/meetings/down loads/slides-2023-09-12/11-COVID-Wallace-508.pdf

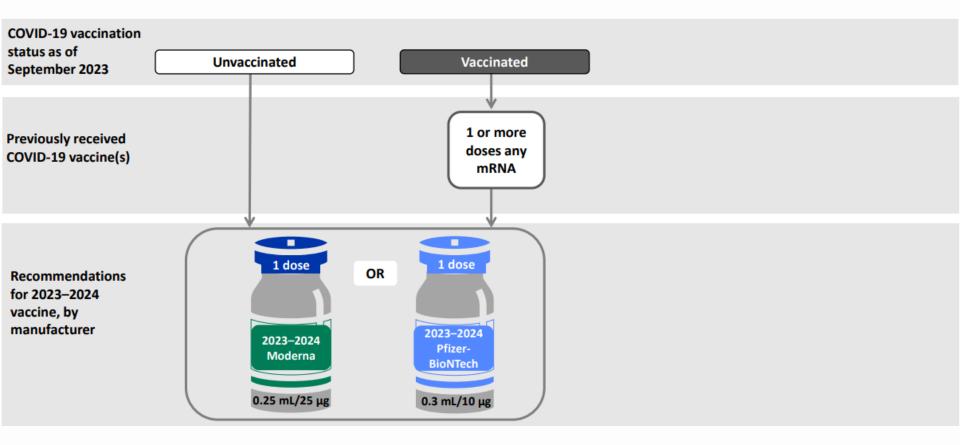
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Updated Recommendations, 6 months-4 years (Not immunocompromised)

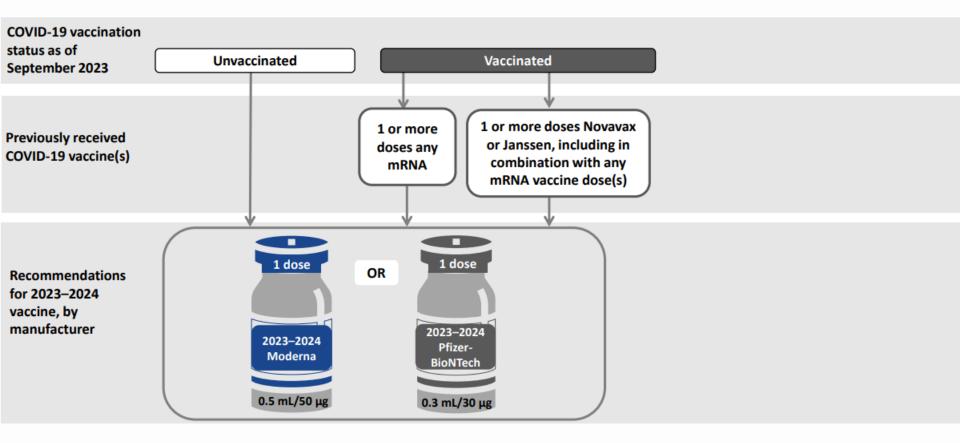




Updated Recommendations, 5-11 years (not immunocompromised)

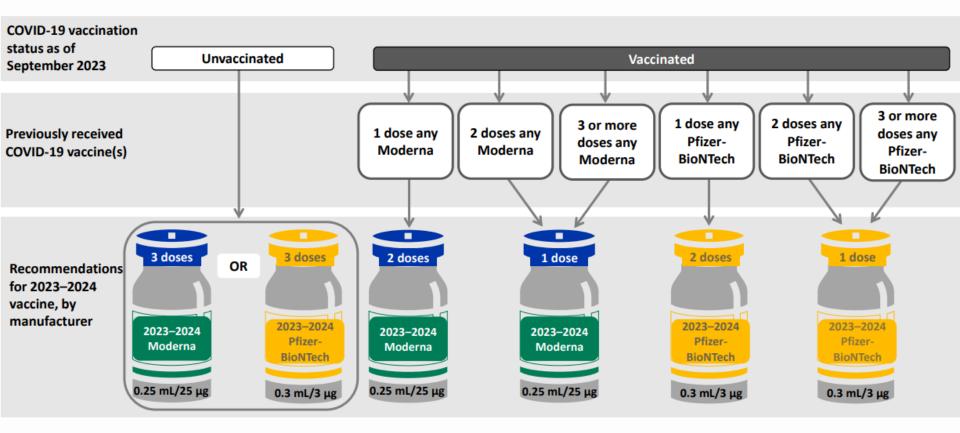


Updated Recommendations, 12 years and older (Not immunocompromised)



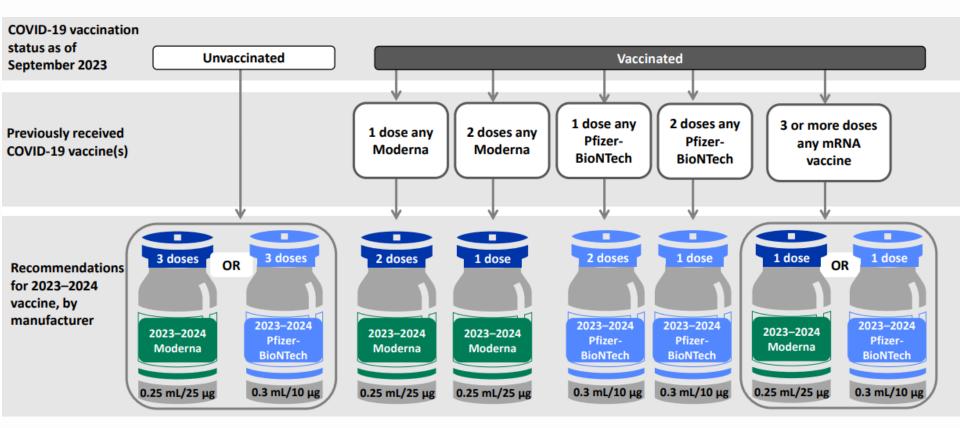


Updated Recommendations, 6 months-4 years Moderately or severely immunocompromised





Updated Recommendations, 6 - 11 years Moderately or severely immunocompromised





Updated Recommendations, 12 years & older Moderately or severely immunocompromised

