
COVID-19 Vaccine Updates: Products and Recommendations

April 24, 2023



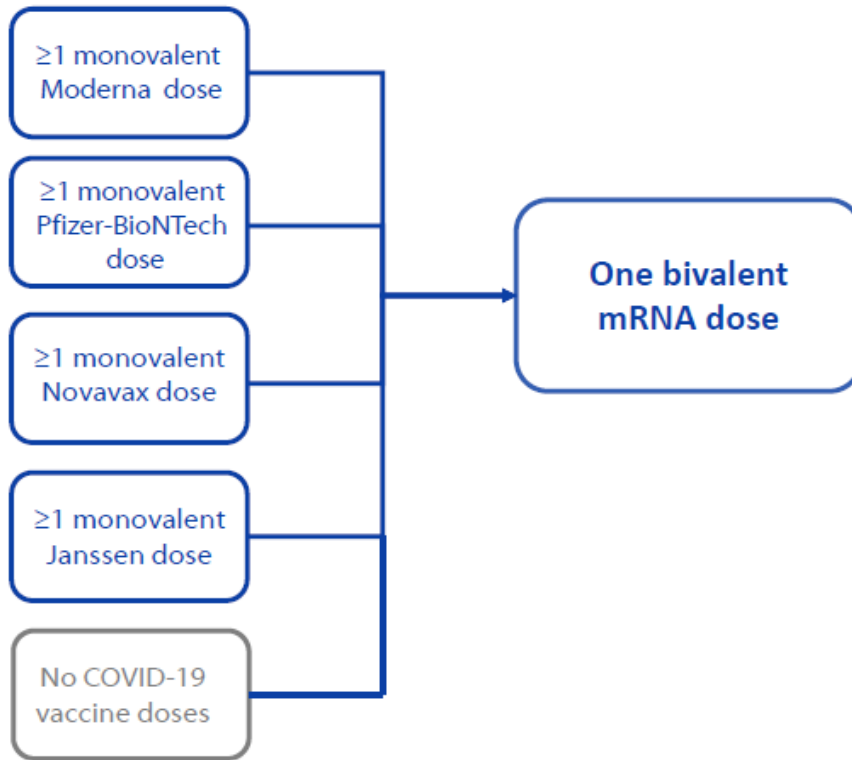
Authorization Updates

- On 4/18, the FDA amended Emergency Use Authorizations (EUAs).
 - Bivalent mRNA vaccines are authorized for all doses administered to individuals 6 months and older.
 - Monovalent mRNA vaccines are no longer authorized for use in the United States.
- On 4/19, the ACIP convened to discuss COVID-19 vaccine recommendation changes, implications and implementation.
- EUA Fact Sheets for [Moderna](#) and [Pfizer](#) have been updated. (EUAs for Novavax and J & J vaccines are not affected by these changes)
- Updated OIP [COVID-19 Immunization Protocol](#) is posted.

Overview of Changes

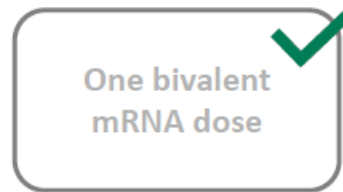
- CDC's new recommendations allow an additional updated (bivalent) vaccine dose for adults ages 65 years and older and additional doses for some people who are immunocompromised. This allows more flexibility for healthcare providers to administer additional doses to some immunocompromised patients as needed.
- Monovalent (original) mRNA COVID-19 vaccines will no longer be recommended for use in the United States.
- CDC recommends that everyone ages 6 years and older receive an updated (bivalent) mRNA COVID-19 vaccine, regardless of whether they previously completed their (monovalent) primary series.
- Individuals ages 6 years and older who have already received an updated mRNA vaccine do not need to take any action unless they are 65 years or older or immunocompromised.
- For young children, multiple doses continue to be recommended and will vary by age, vaccine, and which vaccines were previously received.

New recommendations for people aged ≥ 6 years without immunocompromise who have not yet received a bivalent mRNA dose, regardless of COVID-19 vaccination history



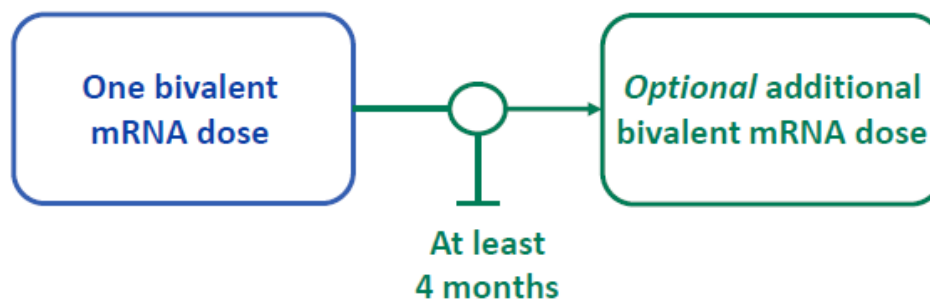
From ACIP Meeting, 4/19/23 at <https://www.cdc.gov/vaccines/acip/meetings/slides-2023-04-19.html>

New recommendations for aged ≥ 6 years without immunocompromise who have already received a bivalent mRNA dose

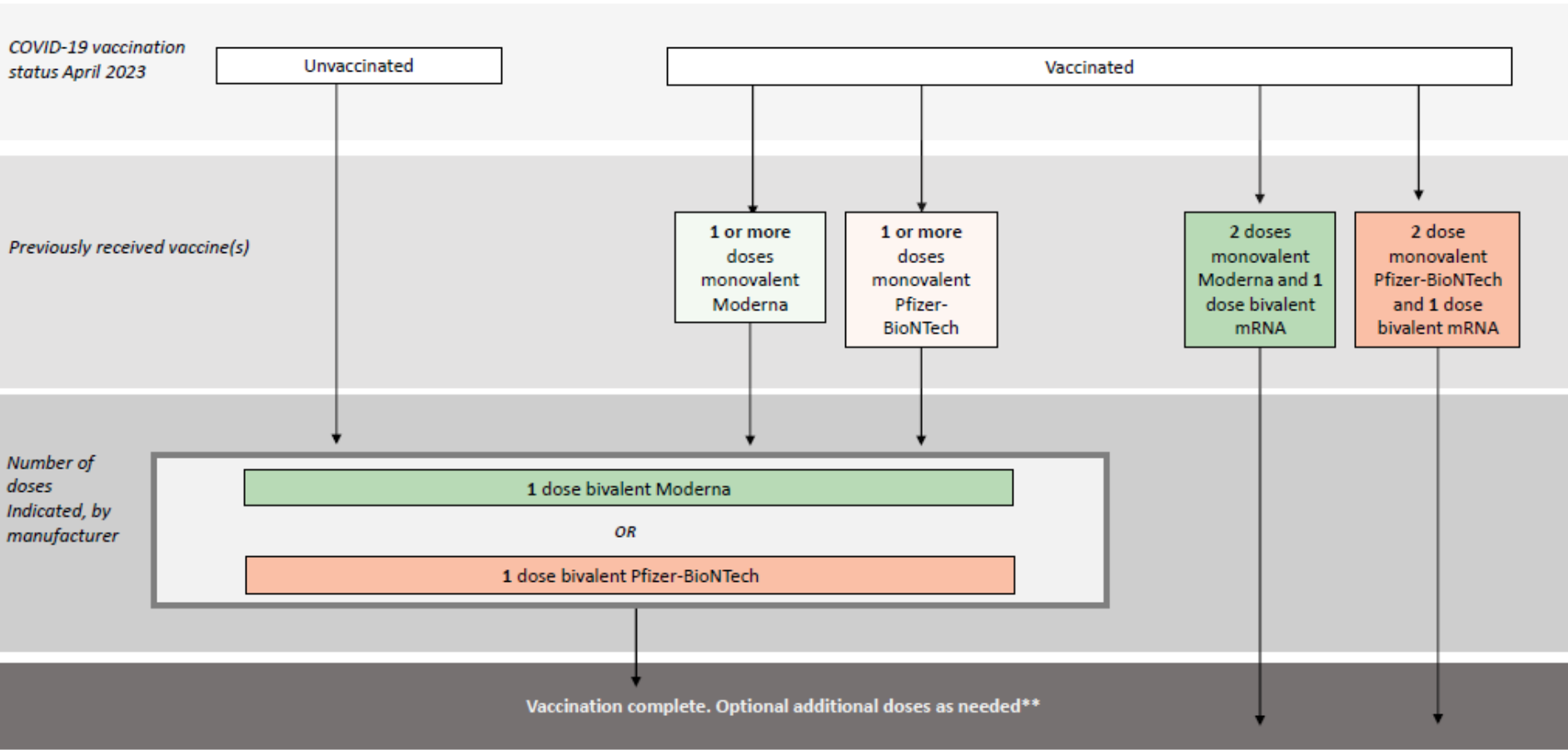


Vaccination is complete.
No doses are indicated at this time.

Flexible for people at higher risk of severe COVID-19: People aged ≥ 65 years who have not yet received a bivalent mRNA dose



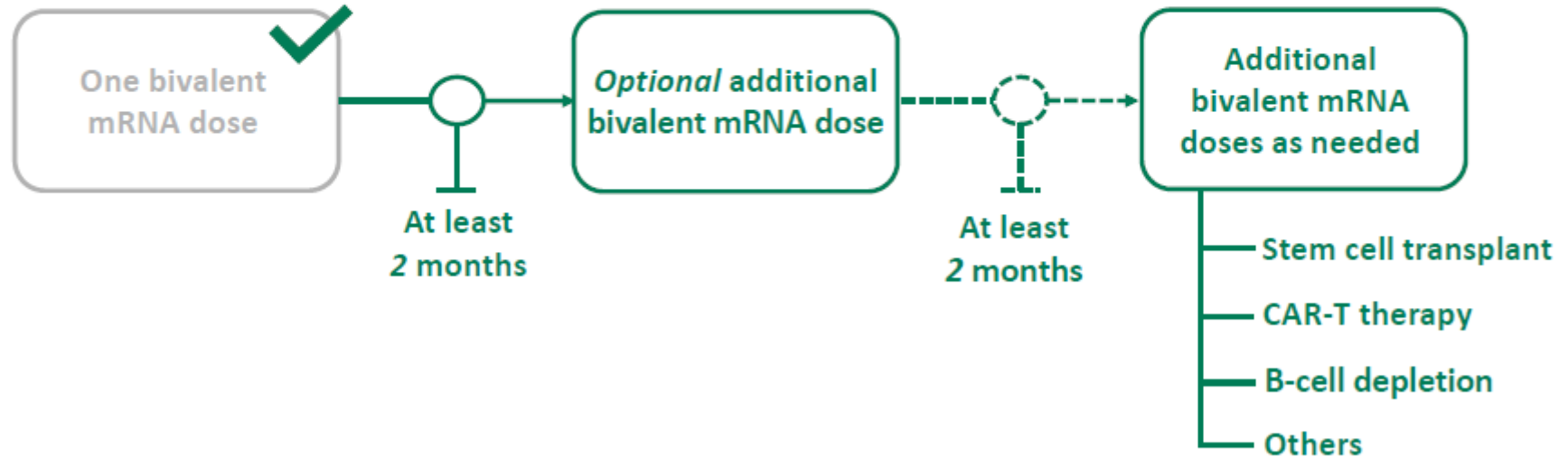
COVID-19 vaccination algorithm for people who are NOT moderately or severely immunocompromised, age 6 years and older, mRNA vaccines April 2023*



*To see product-specific doses and intervals of administration, see reference Table 1 in Interim Clinical Considerations, forthcoming.

**People ages 65+ have the option to receive 1 additional bivalent mRNA dose at least 4 months after the first dose of a bivalent mRNA vaccine.

New flexibility for people at higher risk of severe COVID-19: People aged ≥ 6 years *with immunocompromise** who have already received a bivalent mRNA dose



*Including those with imminent immunocompromise (e.g., prior to organ transplant; other causes.)

From ACIP Meeting, 4/19/23 at <https://www.cdc.gov/vaccines/acip/meetings/slides-2023-04-19.html>

New Recommendations for 6 months – 5 years

Not Immunocompromised

Moderna

6 mo - 5 yrs: At least 2 doses in total, at least one needs to be bivalent.

Pfizer

6 mo - 4 yrs: At least 3 doses in total, at least one needs to be bivalent.

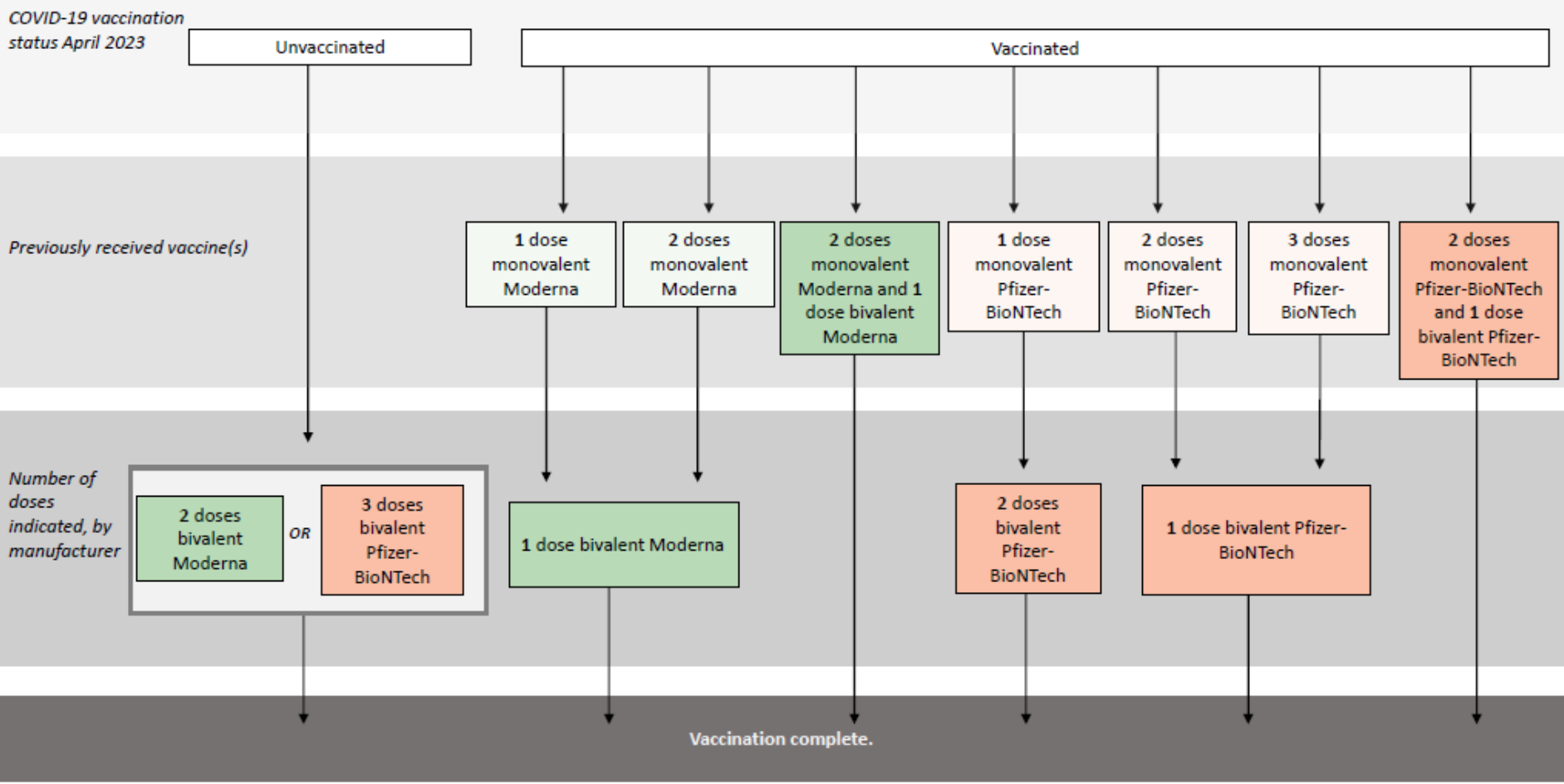
5 year olds: At least one bivalent dose.

With Immunocompromise (See protocol or EUA for specific guidance)

Moderna: Additional Moderna bivalent doses may be administered for children 6 months through 5 years who have received 2 Moderna doses previously.

Pfizer: Additional Pfizer bivalent doses may be administered for children 5 years or older. No additional doses authorized for <5 years at this time.

COVID-19 vaccination algorithm for people without immunocompromise, ages 6 months–4 years, mRNA vaccines April 2023*



*To see product-specific doses and intervals of administration, see Table 1 and 2 forthcoming in Interim Clinical Considerations, forthcoming.

From ACIP Meeting, 4/19/23 at <https://www.cdc.gov/vaccines/acip/meetings/slides-2023-04-19.html>

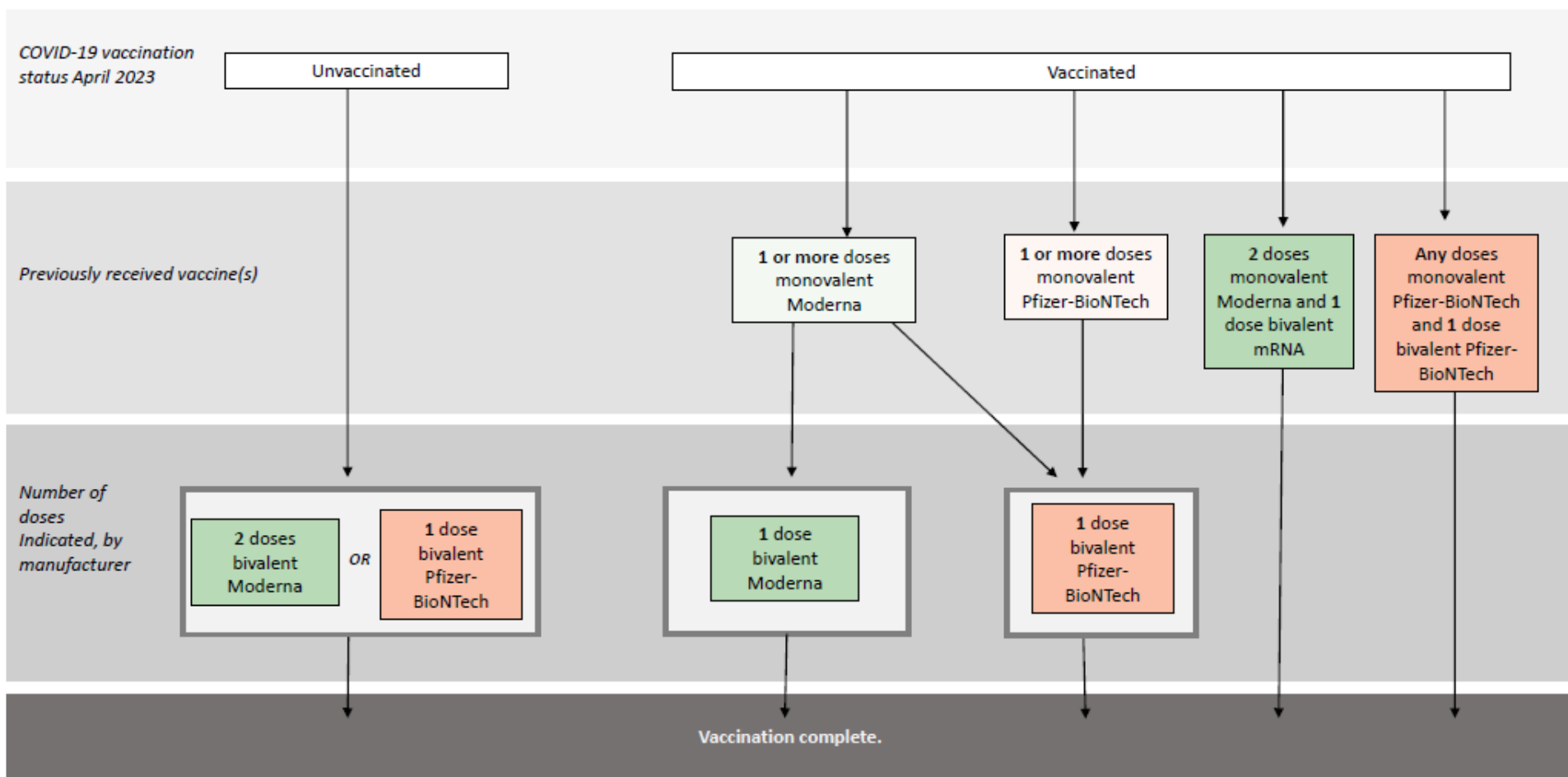


Table 1. COVID-19 vaccination schedule for people who are NOT moderately or severely immunocompromised by COVID-19 vaccination history, April 2023: Ages 6 months–4 years

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
Unvaccinated	Moderna ____or____	2	0.25 mL/25 ug	Dark blue cap; gray label border	Dose 1 and Dose 2: 4–8 weeks
	Pfizer BioNTech	3	0.2 mL/3 ug	Maroon	Dose 1 and Dose 2: 3–8 weeks Dose 2 and dose 3: At least 8 weeks
1 dose monovalent Moderna	Moderna	1	0.25 mL/25 ug	Dark blue cap; gray label border	4-8 weeks after monovalent dose
2 doses monovalent Moderna	Moderna	1	0.2 mL/10 ug	Dark pink cap; yellow label border	At least 8 weeks after last monovalent dose
2 doses monovalent Moderna and 1 dose bivalent Moderna	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA
1 dose monovalent Pfizer-BioNTech	Pfizer BioNTech	2	0.2 mL/3 ug	Maroon	Dose 1: 3–8 weeks after monovalent dose Dose 1 and Dose 2: At least 8 weeks
2 doses monovalent Pfizer-BioNTech	Pfizer BioNTech	1	0.2 mL/3 ug	Maroon	At least 8 weeks after last monovalent dose
3 doses monovalent Pfizer-BioNTech	Pfizer BioNTech	1	0.2 mL/3 ug	Maroon	At least 8 weeks after last monovalent dose
2 doses monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer-BioNTech	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA

From ACIP Meeting, 4/19/23 at <https://www.cdc.gov/vaccines/acip/meetings/slides-2023-04-19.html>

COVID-19 vaccination algorithm for people without immunocompromise, age 5 years, mRNA vaccines April 2023*



*To see product-specific doses and intervals of administration, see reference Table 1 in Interim Clinical Considerations, forthcoming

From ACIP Meeting, 4/19/23 at <https://www.cdc.gov/vaccines/acip/meetings/slides-2023-04-19.html>

Table 1. COVID-19 vaccination schedule for people who are NOT moderately or severely immunocompromised by COVID-19 vaccination history, April 2023: Age 5 years

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
Unvaccinated	Moderna ___or___	2	0.25 mL/25 ug	Dark blue cap; gray label border	Dose 1 and Dose 2: 4–8 weeks
	Pfizer BioNTech	1	0.2 mL/10 ug	Orange	
1 dose monovalent Moderna	Moderna ___or___	1	0.25 mL/25 ug	Dark blue cap; gray label border	4–8 weeks after monovalent dose
	Pfizer BioNTech	1	0.2 mL/10 ug	Orange	At least 8 weeks after monovalent dose
2 doses monovalent Moderna	Moderna ___or___	1	0.2 mL/10 ug	Dark pink cap; yellow label border	At least 8 weeks after last monovalent dose
	Pfizer BioNTech	1	0.2 mL/10 ug	Orange	At least 8 weeks after last monovalent dose
2 doses monovalent Moderna and 1 dose bivalent mRNA	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA
1 or more doses monovalent Pfizer-BioNTech	Pfizer-BioNTech	1	0.2 mL/10 ug	Orange	At least 8 weeks after last monovalent dose
2 doses monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer-BioNTech	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA

From ACIP Meeting, 4/19/23 at <https://www.cdc.gov/vaccines/acip/meetings/slides-2023-04-19.html>



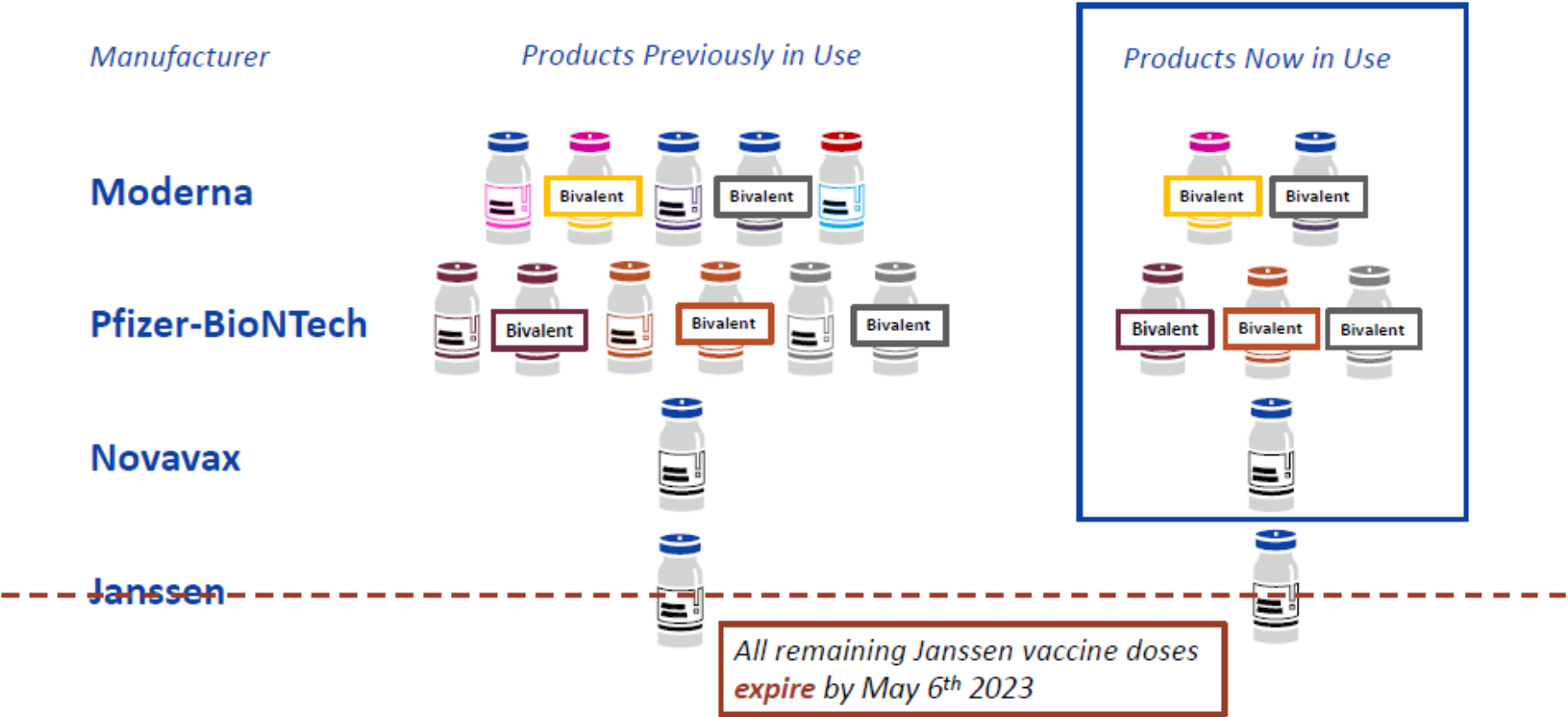
Stay Up to Date with COVID-19 Vaccines

Let's Review!

- Adults and children aged 6 years and older are up to date with COVID-19 vaccines if they got a bivalent (updated) COVID-19 vaccine. (Any time in the past)
- Children 6 months through 5 years of age who received the Pfizer-BioNTech COVID-19 vaccine are up to date if:
 - They are 6 months to 4 years of age and got at least 3 COVID-19 vaccine doses, including at least one bivalent (updated) COVID-19 vaccine dose.
 - They are 5 years of age and got at least 1 bivalent (updated) COVID-19 vaccine dose.
- Children 6 months through 5 years of age who got the Moderna COVID-19 vaccine are up to date if they got at least two Moderna COVID-19 vaccine doses, including at least one bivalent (updated) COVID-19 vaccine dose. *5 year olds who received Moderna can receive either a bivalent Moderna or Pfizer dose
- You may be eligible for additional COVID-19 vaccine doses if:
 - You are 65 years of age and older and got your first bivalent (updated) COVID-19 vaccine booster 4 or more months ago.
 - You are moderately or severely immunocompromised and received a bivalent (updated) COVID-19 vaccine booster 2 or more months ago.
- If you are unable or choose not to get a recommended bivalent mRNA vaccine, you will be up to date if you got the Novavax COVID-19 vaccine doses approved for your age group.



From ACIP Meeting, 4/19/23 at <https://www.cdc.gov/vaccines/acip/meetings/slides-2023-04-19.html>

Fewer COVID-19 Vaccine Products in Use






From ACIP Meeting, 4/19/23 at <https://www.cdc.gov/vaccines/acip/meetings/slides-2023-04-19.html>


Moderna **Bivalent** COVID-19 Vaccine Products

Authorized Age Group	 6 months – 5 years (specific situations)	 6 months and older (most doses)
Vial cap color	Dark Pink	Dark blue
Dosage	10 mcg	25 mcg (6m-11) 50 mcg (12+)
Injection volume	0.2 mL	0.25 mL (6m-11) 0.5 mL (12+)
Dilution required	No	No
Storage & Handling	Standard freezer (-50° to -15° C) until expiration date. Refrigerator (2° to 8° C) for up to 30 days. Protect from light. Do not refreeze. Room temperature up to 24 hrs. After first puncture, discard any remaining doses: pink cap after 8 hrs / dark blue cap after 12 hrs.	

Pfizer **Bivalent** COVID-19 Vaccine Products

Authorized Age Group	 6 months – 4 years	 5 – 11 years	 12 years and older
Vial cap color	Maroon	Orange	Gray
Doses/vial	10	10	Single dose & Multi-dose (6)
Dose (mRNA concentration)	3 mcg	10 mcg	30 mcg
Injection volume	0.2 mL	0.2 mL	0.3 mL
Dilution required	Yes (2.2 mL)	Yes (1.3 mL)	No
Storage & Handling	Ultracold freezer (-90° to -60° C) until expiration date. Refrigerate (2° to 8° C) up to 10 weeks. Protect from light. Do not refreeze. May be stored at room temperature up to 12 hours. Discard any remaining vaccine after 12 hours.		

Novavax Monovalent COVID-19 Vaccine Product

<p>Authorized Age Group</p>		<p>Primary Series: 12 yrs and older Booster: 18 yrs and older in limited situations</p>
<p>Vial cap color</p>	<p>Dark blue</p>	
<p>Dose</p>	<p>5 mcg antigen + 50 mcg adjuvant</p>	
<p>Injection volume</p>	<p>0.5 mL</p>	
<p>Dilution required</p>	<p>No</p>	
<p>Schedule</p>	<p>Primary series: 2 doses, 3 weeks apart Booster dose: 1 bivalent mRNA dose at least 2 months after last primary series dose is recommended.* <i>*If 18 or older, has not received a previous booster dose and unable or unwilling to receive an mRNA bivalent booster, one Novavax booster dose should be administered 6 months after last primary series dose.</i></p>	
<p>Storage & Handling</p>	<p>Refrigerate until expiration. Protect from light. Discard 6 hours after first puncture.</p>	

Manufacturer Trainings & Resources Available

- **Pfizer** vaccine trainings, live and on-demand content: <https://www.pfizermedicalinformation.com/en-us/medical-updates>
- **Moderna** has live trainings and educational resources available on their website: <https://eua.modernatx.com/covid19vaccine-eua/providers/resources>
- **Novavax Webinars** hosts Office Hours each week. Register for upcoming webinars: <https://novav.ax/officehours>

Waste all Monovalent Pfizer & Moderna

Discard monovalent inventory (including Spikevax & Comirnaty)

- 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 monovalent inventory

1. 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
2. Report all spoiled/wasted/expired doses using our Smartsheet and clicking on the "Wasted Vaccine Survey" link in the lower-left: [Wasted/Spoiled/Expired Vaccine Dashboard - Smartsheet.com](#)

Check Expiration Dates Weekly

Online expiry lookup tools:

Moderna: <https://modernacovid19global.com/vial-lookup>

Pfizer: <https://lotexpiry.cvdvaccine.com/>

Novavax: <https://us.novavaxcovidvaccine.com/hcp>

Janssen: <https://vaxcheck.jnj/>

Remove expired vaccine from storage units and dispose of according to your agency's medical waste policy. COVID-19 vaccine is not returnable and is reported using the [Wasted Vaccine Survey](#). Remember to adjust your inventory in ALERT IIS too.

If expired vaccine is inadvertently administered:

- Review guidance on the CDC website: [Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendices, References, and Previous Updates | CDC](#).
- Report vaccine administration errors to the [Vaccine Adverse Event Reporting System](#).

Is administration of a monovalent mRNA vaccine a vaccine error?

Per CDC, 4/24/23:

“It would be considered an error as soon as the monovalent vaccines were no longer authorized (no grace period).

For efficiency, if this same error occurred multiple times (e.g., a clinic vaccinated with monovalent all day and didn’t see the EUA until the next day), providers can submit a batch report. The single VAERS report should:

- Describe what the error was, how it happened, and how many people were affected.
- If anybody affected by the vaccination error developed adverse events after that error, they could file a VAERS report individually.”

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

Additional Help for Providers is on the Way

- CDC's [Interim Clinical Considerations](#) for the Use of Authorized COVID-19 Vaccines will be updated with comprehensive tables of vaccine doses and dosages indicated.
 - For each age group
 - By COVID-19 vaccine history (children ages 6 months through 5 yrs)
- Revision of clinical guidance materials is underway
- COCA Call to be held May 11th
Please visit <https://emergency.cdc.gov/coca/> for details.