

Information on COVID-19 Vaccine (2023-2024 Formulation)

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General Information/ Key Talking Points on 2023-2024 COVID-19 Vaccine

- The U.S. Food and Drug Administration and the CDC have authorized updated COVID-19 vaccines for everyone 6 months and older to protect against serious illness from COVID-19.
- mRNA vaccines (Moderna and Pfizer) are authorized for those 6 months and older while a protein subunit vaccine (Novavax) is authorized for those 12 years and older.
- Each of the updated vaccines are safe and highly effective in protecting against serious illness from COVID-19; there is no preference for use of one vaccine over another.
- The updated vaccines are monovalent (single target), targeting the Omicron XBB.1.5 sublineage of SARS-CoV-2 and is expected to provide protection against current circulating Omicron variants. The previously available bivalent vaccines (which included both the original SARS-CoV-2 strain and earlier Omicron variants that are no longer in circulation) are no longer authorized for use.

Visit the [U.S. Food and Drug Administration website](#) and [U.S. Centers for Disease Control and Prevention's website](#) for more information regarding COVID-19 vaccines.

What is different about the 2023-2024 COVID-19 vaccine compared to last year's vaccine?

The updated COVID-19 vaccine is a monovalent vaccine based on the Omicron XBB.1.5 sublineage of SARS-CoV-2. Most of the current circulating variants are descended from or closely related to XBB.1.5 and the vaccine is expected to provide protection against these strains. The original monovalent and most recent bivalent (original and Omicron BA.4/ BA.5) COVID-19 formulations are not active against current circulating variants and are no longer available for use.

Who is eligible to get the 2023-2024 COVID-19 vaccine?

The general public:

Updated COVID-19 vaccines have been approved and are recommended for everyone ages 6 months and older in the United States.

- Individuals 12 years of age and older are eligible for a single dose of the updated Moderna, Pfizer, or Novavax COVID-19 vaccine if it has been at least 8 weeks since their most recent dose of any COVID-19 vaccine.
- Individuals from >6 months - <12 years are eligible for a single dose of the updated Moderna or Pfizer COVID-19 mRNA vaccines; Novavax vaccine is not licensed for this age group.
- If someone has not received the primary series of COVID-19 vaccination, a single dose of the 2023-24 formulation either of the Moderna or Pfizer-BioNTech vaccines, or two doses of the updated Novavax vaccine (only for those ≥ 12 years of age), now qualify as completion of a primary series.
- Source: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html>

Patients: Which COVID-19 vaccines are available to patients this season?

Starting Monday, October 23, 2023, Fred Hutch will be offering the updated 2023-2024 COVID-19 mRNA vaccine from Pfizer to patients. Patients can also get their COVID-19 vaccine (from any of the available manufacturers) at local retail pharmacies.

Employees: How can I get the updated 2023-2024 COVID-19 vaccine? Is it mandatory?

- Fred Hutch Cancer Center is offering the updated vaccine (started October 10, 2023).
- Fred Hutch has limited appointments for the COVID-19 updated vaccine available to staff for four dates in Oct until Nov 2 at the SLU campus, see the COVID-19 Vaccination program site. Staff can also get the updated vaccine elsewhere in your community at local pharmacies and clinics where it is readily available. Please check with your insurer to confirm coverage.
- Employees are strongly encouraged, but not required, to get the updated 2023-2024 Covid-19 vaccine.
- If you receive your updated 2023-2024 Covid vaccine this year, healthcare workers must submit your vaccine documentation using the COVID-19 Vaccination Status Form Questionnaire in the Enterprise Health Portal as outlined below.

More information: <https://centernet.fredhutch.org/cn/u/ehs/covid-19-vaccination-program.html>.

What are recommendations for use of the 2023-2024 COVID-19 vaccine for Immunosuppressed patients?

The updated 2023-2024 COVID-19 vaccines are recommended for immunosuppressed individuals including cancer patients. Administration of COVID-19 vaccine should not be delayed in patients receiving immunosuppression but whenever possible, it should be administered at least 2 weeks before initiation or resumption of immunosuppressive therapies. Recommendations for individuals 12 years of age and older are included below:

COVID-19 Vaccination history prior to updated 2023-2024 vaccine	Number of 2023-2024 COVID-19 vaccine doses indicated	Interval between doses
≥ 3 doses of any mRNA (Pfizer or Moderna) vaccine	1 dose of Pfizer, Moderna, or Novavax	At least 8 weeks after last dose
≥ 2 doses of any mRNA (Pfizer or Moderna) vaccine	1 dose of Pfizer or Moderna	At least 4 weeks after last dose
≥ 1 dose of Novavax or Janssen, including in combination with any mRNA vaccine	1 dose of Pfizer, Moderna, or Novavax	At least 8 weeks after last dose
1 dose Pfizer or Moderna	2 doses of Pfizer or Moderna	Dose 1: At least 3 weeks after last dose Dose 1 and Dose 2: At least 4 weeks
Unvaccinated	3 doses of Pfizer or Moderna OR 2 doses of Novavax	Dose 1 and Dose 2: At least 4 weeks Dose 2 and Dose 3: At least 4 weeks

- For recommendations for immunosuppressed children < 12, please refer to the
- Recipients of HCT or CAR-T-cell therapy who received 1 or more doses of COVID-19 vaccine prior to or during treatment should be revaccinated. Revaccination should start at least 3 months (12 weeks) after transplant or CAR-T-cell therapy and should follow the currently recommended schedule for people who are unvaccinated immunosuppressed patients and receive at least 3 doses of the vaccine (at least 4 weeks

apart). Revaccination may also be considered for individuals who received 1 or more doses of COVID-19 vaccine during treatment with B cell-depleting therapies, 6 months after completion of the B-cell depleting therapy is the suggested interval to start revaccination. For patients who receive B-cell depleting therapies on a continuing basis, the COVID-19 vaccine should be administered approximately 4 weeks before the next scheduled therapy.

What are the recommendations for people with a history of myocarditis and pericarditis after COVID-19 vaccine?

- Individuals who developed myocarditis or pericarditis within 3 weeks after a dose of COVID-19 vaccine should generally not receive a subsequent dose of COVID-19 vaccine. If, after a risk assessment, the decision is made to administer a subsequent COVID-19 vaccine dose, wait until at least after their episode of myocarditis or pericarditis has resolved (resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by patient's clinical team). Decisions should be made in close consultation with the primary team and the patient's cardiologist if applicable.
- Individuals who have a history of myocarditis or pericarditis that occurred before COVID-19 vaccination or > 3 weeks after COVID-19 vaccination may receive the COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved. This includes people who had myocarditis or pericarditis due to SARS CoV-2 or other viruses.

The recommendations are outlined in more depth at <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html>

Why do we need a new vaccine?

As the virus continues to evolve, the 2023-2024 COVID-19 vaccine has been updated to provide protection against current circulating variants. Immune responses also wane over time after COVID-19 vaccination. The updated vaccines target currently circulating variants, improve antibody responses to provide protection against serious illness from COVID-19.

I have or recently had COVID-19. Should I still get the updated vaccine?

People with known current SARS-CoV-2 infection should defer any COVID-19 vaccination, including the updated vaccine, at least until recovery from the acute illness (if symptoms were present) and/or criteria to discontinue isolation in the clinic have been met.

In addition, people who recently had SARS-CoV-2 infection may consider delaying vaccination (either primary series or updated vaccine booster) by 3 months from symptom onset or positive test (if infection was asymptomatic). Studies have shown that increased time between infection and vaccination may result in an improved immune response to vaccination. Also, a low risk of reinfection has been observed in the weeks to months following infection. Individual factors such as risk of COVID-19 severe disease, COVID-19 community level, or characteristics of the predominant SARS-CoV-2 strain should be taken into account when determining whether to delay getting a COVID-19 vaccination after infection.

What if I received the bivalent booster shot, am I eligible for the updated vaccine?

Yes, those who previously received the bivalent booster (or any other prior COVID-19 vaccinations) are eligible and recommended to receive the updated vaccine 2 months after their last shot.

Can I still get the previous booster if I want to?

No. The FDA has removed the authorization for the monovalent original mRNA vaccine and for the most-recent bivalent booster. The 2023-2024 updated vaccines are the only ones currently approved for use by the FDA.

Can I get the updated 2023-2024 vaccine if I received the Pfizer-BioNTech, Moderna, Novavax or Janssen/Johnson & Johnson primary vaccines?

Yes. Regardless of which primary vaccine you received, everyone is eligible for the updated COVID-19 vaccine. You can receive either the Moderna, Pfizer-BioNTech, or Novavax updated vaccine regardless of the manufacturer of your prior vaccination series. The Johnson & Johnson/Janssen vaccine is no longer available for use and has not been updated.

Do you expect us to need updated vaccines every year?

We expect that updated vaccines may be needed to target changes in circulating variants in the future, similar to influenza vaccines, but it depends on how the virus continues to evolve.

Are there any additional side effects of the updated COVID-19 vaccine over prior COVID-19 vaccines?

No. Reactions to the Moderna, Pfizer-BioNTech and Novavax updated vaccines were similar to the side effect profiles of prior approved COVID-19 vaccines.

Is it safe to get the updated COVID-19 vaccine and updated flu vaccine at the same time?

Studies indicate that it's safe and effective to get the flu vaccine and updated COVID-19 vaccine at the same time. Per Fred Hutch policy and CDC, flu and COVID-19 vaccines may be administered in the same arm (at least an inch apart) or different arms. **However, to reduce side effects, administer one vaccine per arm.** If unable to give vaccine in a certain arm, administering both in one arm is appropriate.

I heard that these updated vaccines haven't been tested in humans. Is that true?

The updated COVID-19 vaccine are very closely related to prior vaccines which were studied in large human clinical trials. The updated vaccines target the new strains of COVID-19 that are circulating, so the viral targets of the available vaccines have changed. Updated vaccines were tested in animal models and small human trials, to assure they provided sufficient immunity against current variants. This is a similar approach we take to updating influenza vaccines each year. Animal models are used to help predict use in humans when the FDA approves updated seasonal influenza vaccines. This is done because of the need to rapidly produce vaccines for

influenza. If human studies were required every year, it would slow down the process of making vaccines available and likely limit their use when needed.

References:

<https://www.cdc.gov/vaccines/covid-19/downloads/covid-19-vacc-schedule-at-a-glance-508.pdf>

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html?s_cid=11706:cdc%20covid%20booster:sem.ga:p:RG:GM:gen:PTN:FY22