



Department of Health

Heidi Hedberg, Commissioner
Anne Zink, MD, Chief Medical Officer

3601 C Street, Suite 540
Anchorage, Alaska 99503

Division of Public Health

Lindsey Kato, Director

<https://health.alaska.gov/dph/Epi>
24 Hour Emergency (800) 478-0084
Local (907) 269-8000

Editors:

Joe McLaughlin, MD, MPH
Liz Ohlsen, MD

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COVID-19 Vaccine for the 2023–24 Fall/Winter Virus Season

Background

- On September 11, 2023, the Food and Drug Administration (FDA) authorized the updated (2023–2024 Formula) COVID-19 mRNA vaccines by Moderna and Pfizer-BioNTech for use in persons aged 6 months–11 years under Emergency Use Authorization (EUA) and approved the updated Moderna and Pfizer-BioNTech COVID-19 vaccines for persons aged ≥12 years.¹
- On October 3, 2023, FDA authorized the updated Novavax COVID-19 vaccine for use in persons aged ≥12 years under EUA.¹
- These vaccines are all monovalent, targeting circulating SARS-CoV-2-XBB-sublineage variants to help protect against COVID-19 hospitalization and death.¹
- While anyone can develop severe COVID-19, adults aged ≥65 years and people with underlying medical conditions are at highest risk for COVID-19 hospitalization.²
- The pooled vaccine effectiveness (VE) of last year’s bivalent mRNA vaccines was 53% (95% CI = 50%–56%) against medically-attended COVID-19, 48% (95% CI = 30%–61%) against hospitalization, and 61% (95% CI = 41%–74%) against death.¹ The certainty assessment for the VE against death was low due to inconsistency.¹

Safety

Post-vaccination reactions were generally similar for Moderna and Pfizer-BioNTech COVID-19 vaccines, including pain at the injection site, fatigue, headache, and myalgia.¹ Any adverse events following vaccination should be reported to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

General Recommendations

- Everyone aged ≥6 months is recommended to receive one dose of the updated 2023–24 COVID-19 vaccine.
- For persons aged ≥5 years, 1 dose of an updated 2023–24 vaccine is recommended, regardless of vaccination history.
- For children aged 5–11 years, an mRNA vaccine (Moderna or Pfizer) is recommended.
- For persons aged ≥12 years, Moderna, Pfizer, or Novavax may be used.
- Children aged 6 months through 4 years should complete a multi-dose initial series with at least one dose of the 2023–24 mRNA COVID-19 vaccine; all doses of COVID-19 vaccine should be from the same manufacturer (either 2 doses of Moderna or 3 doses of Pfizer).³
- If a child has completed the primary series with the original monovalent or bivalent vaccines, an additional dose of 2023–24 updated mRNA COVID-19 vaccine should be given of the same manufacturer.³
- For patients who have received prior COVID-19 vaccine doses, the updated vaccine should be administered ≥2 months following the most recent dose.¹

- Coadministration (e.g., with influenza or respiratory syncytial virus vaccines), is recommended for children, adolescents, and adults if there are no contraindications at the time of the health care visit.³

Recommendations for Immunocompromised People

- People who are moderately or severely immunocompromised should receive a 3-dose initial mRNA vaccination series using vaccines from the same manufacturer or a 2-dose Novavax series.³
- If a patient has received 1 previous dose, they should receive 2 doses of updated 2023–24 COVID-19 vaccine.³
- If a patient has received ≥2 prior doses, they should receive 1 dose of the 2023–24 COVID-19 vaccine.³

Precautions and Contraindications

A summary of precautions and contraindications is provided below (Table).

Vaccine Availability

- Under the Affordable Care Act, any COVID-19 vaccine that is authorized or approved by the FDA is required to be covered, without cost-sharing requirements, by group health plans and health insurance issuers offering group or individual health insurance coverage.¹
- As such, COVID-19 vaccines are covered through private insurance, Medicare Part B, Medicaid, the Federal Vaccines for Children Program (VFC), and the Alaska Vaccine Assessment Program (AVAP).
- Uninsured adults are eligible for COVID-19 vaccines through AVAP or the [Bridge Access Program](#), a public-private partnership serving as a temporary measure to maintain access to COVID-19 vaccines for un/underinsured adults (working through public health clinics and participating retail pharmacies).¹
- Vaccine appointments, including those for the Bridge Access Program, can be found at [vaccines.gov](#).
- Pharmacies, health care clinics, and other facilities may offer COVID-19 vaccines.

References

- MMWR. Use of Updated COVID-19 Vaccines 2023-2024 Formula for Persons Aged ≥6 Months: Recommendations of the Advisory Committee on Immunization Practices—United States, September 2023. October 10, 2023. 72. Available: https://www.cdc.gov/mmwr/volumes/72/wr/mm7242e1.htm?s_cid=mm7242e1_w
- MMWR. COVID-19-Associated Hospitalizations Among U.S. Adults Aged ≥65 Years—COVID-19-NET, 13 States, January–August 2023. 72(40);1089-1094 Available at: <https://www.cdc.gov/mmwr/volumes/72/wr/mm7240a3.htm>
- CDC. Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States. Updated September 15, 2023. Available at: <https://www.cdc.gov/vaccines/COVID-19/clinical-considerations/interim-considerations-us.html#COVID-19-vaccines>

Table. Contraindications and Precautions to COVID-19 Vaccination³

| Medical condition or history | Guidance | Recommended action |
|---|------------------|--|
| History of a severe allergic reaction (e.g., anaphylaxis†) after a previous dose or to a component of the COVID-19 vaccine‡ | Contraindication | Do not vaccinate with the same COVID-19 vaccine type.§ May administer the alternate COVID-19 vaccine type.§ |
| History of a diagnosed non-severe allergy to a component of the COVID-19 vaccine‡ | Precaution | May administer the alternate COVID-19 vaccine type.§ |
| Moderate or severe acute illness, with or without fever | Precaution | Defer vaccination until the illness has improved. |
| History of multisystem inflammatory syndrome (MIS-C or MIS-A) | Precaution | Review clinical considerations. ³ |
| Myocarditis or pericarditis ≤3 weeks after a COVID-19 dose | Precaution | Generally avoid a subsequent dose of any COVID-19. |

†See [package inserts](#) and [FDA EUA fact sheets](#) for a full list of vaccine ingredients. mRNA COVID-19 vaccines contain polyethylene glycol (PEG).

§Vaccine type refers to mRNA (Moderna and Pfizer-BioNTech) or protein subunit vaccines (Novavax)