

Emergency Use Instructions for Healthcare Providers: **Additional Doses of 2024-2025 Formula COVID-19 Vaccine by Moderna**

The Centers for Disease Control and Prevention (CDC) is issuing Emergency Use Instructions (EUI) to provide information about the use of the 2024-2025 Formula¹ COVID-19 vaccine by Moderna (Spikevax²), which is approved (licensed) by the Food and Drug Administration (FDA) for the prevention of COVID-19 in individuals ages 12 years and older. The CDC-issued EUI provide information for the uses of this vaccine that are beyond the FDA-approved labeling. The CDC-issued EUI provide information on the following uses of the 2024-2025 Formula COVID-19 vaccine by Moderna for:

- Additional doses for people ages 12 years and older who are moderately or severely immunocompromised, which include the following:
 - A 3-dose initial series for people ages 12 years and older who are moderately or severely immunocompromised and previously unvaccinated or who need revaccination. People who need revaccination are those who are moderately or severely immunocompromised who received COVID-19 vaccine dose(s) during treatment with B-cell-depleting therapies over a limited period or who received COVID-19 vaccine dose(s) prior to or during treatment involving hematopoietic cell transplant or chimeric antigen receptor (CAR)-T-cell therapy.
 - People ages 12 years and older who are moderately or severely immunocompromised and have previously received 1 original monovalent, bivalent, or 2023-2024 Formula mRNA COVID-19 vaccine dose are recommended to receive 2 homologous (i.e., from the same manufacturer) 2024-2025 Formula mRNA vaccine doses to complete the 3-dose initial series.
 - People ages 12 years and older who are moderately or severely immunocompromised and have previously received 2 original monovalent, bivalent, or 2023-2024 Formula mRNA COVID-19 vaccine doses are recommended to receive 1 homologous 2024-2025 Formula mRNA vaccine dose, at least 4 weeks after their last COVID-19 vaccine dose.
 - For people initiating or completing the 3-dose initial series with the Moderna COVID-19 vaccine, Dose 1 and Dose 2 are recommended with a 4-week interval; Dose 2 and Dose 3 are recommended with at least a 4-week interval.
 - People ages 12 years and older who are moderately or severely immunocompromised and are previously vaccinated with an initial vaccine series may receive more than 1 dose of the 2024-2025 Formula COVID-19 vaccine by Moderna, Pfizer-BioNTech, or Novavax, informed by the clinical judgment of a healthcare provider and personal preference and circumstances.

The EUI for the 2024-2025 Formula COVID-19 vaccine by Pfizer-BioNTech also allow the same uses as an alternative 2024-2025 Formula mRNA COVID-19 vaccine to Moderna (see the [Pfizer-BioNTech COVID-19 EUI Fact Sheet for Healthcare Providers](#)). The 2024-2025 Formula COVID-19 vaccine by Novavax, which is authorized under Emergency Use Authorization (EUA; see the [Novavax EUA Fact Sheet](#)) is also available and the same recommendations to the 2024-2025 Formula Moderna COVID-19 vaccine for the 2024-2025 Formula Novavax vaccine are available in the [Interim Clinical Considerations](#).

Refer to CDC's [Interim Clinical Considerations](#) for specific recommendations on use of the 2024-2025 Formula COVID-19 vaccine by Moderna allowed under the EUI. For additional information about the COVID-19 vaccine by Moderna COVID-19, refer to the [Spikevax package insert](#).

What are EUI and why is CDC issuing EUI for the 2024-2025 Formula COVID-19 vaccine by Moderna?

In 2013, the Pandemic and All-Hazards Preparedness Reauthorization Act included a new provision that allowed for the issuance of EUI to permit CDC to inform healthcare providers and recipients about certain uses of FDA-approved, licensed, or cleared medical products. Specifically, EUI inform healthcare providers and recipients about such products' approved, licensed, or cleared conditions of use by noting additional uses under EUI.

¹ The 2024-2025 Formula COVID-19 vaccine by Moderna encodes the spike protein of SARS-CoV-2 Omicron variant lineage KP.2 (Omicron KP.2).

² Spikevax is the proprietary name for the product licensed under the Biologics License Application (BLA). Because Spikevax may be commonly referred to as the "Moderna COVID-19 Vaccine," these EUI refer to this vaccine as the COVID-19 vaccine by Moderna.

Moderna COVID-19 Vaccine EUI Healthcare Providers Fact Sheet, ver 8/30/2024; originally CDC-issued 2/11/2022; prior revisions in 2022 (2/22, 3/29, 5/20, 6/24, 9/02); 2023 (9/12, 10/6)); 2024 (2/29, 8/23)

The 2024-2025 Formula COVID-19 vaccine by Moderna is approved by the FDA as a single dose for active immunization to prevent COVID-19 in people ages 12 years and older to be administered at least 2 months after the last dose of COVID-19 vaccine. CDC is issuing these EUI to provide information about use of the 2024-2025 Formula COVID-19 vaccine by Moderna for additional doses for people ages 12 years and older who are moderately or severely immunocompromised that extend beyond its FDA-approved labeling as described further under “Who can receive additional doses of the 2024-2025 Formula COVID-19 vaccine by Moderna?” and “What are the doses and intervals of the 2024-2025 Formula COVID-19 vaccine by Moderna for people ages 12 years and older who are moderately or severely immunocompromised?”.

What is COVID-19?

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by SARS-CoV-2 that emerged in late 2019. It is predominantly a respiratory illness but can also affect other organs. People with SARS-CoV-2 infection have reported a wide range of symptoms, ranging from no symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include fever or chills, cough, shortness of breath, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, and diarrhea.

Who can receive additional doses of the 2024-2025 Formula COVID-19 vaccine by Moderna?

The below describes who can receive the 2024-2025 Formula COVID-19 vaccine by Moderna under these EUI. The COVID-19 vaccine by Pfizer-BioNTech can also be used under EUI for the same uses as an alternative 2024-2025 Formula mRNA COVID-19 vaccine (see the [Pfizer-BioNTech EUI Fact Sheet for Healthcare Providers](#)). In addition, the 2024-2025 Formula COVID-19 vaccine by Novavax is available for persons ages 12 years and older (see the [Interim Clinical Considerations](#) or [Novavax EUA Fact Sheet](#)).

- People ages 12 years and older who are moderately or severely immunocompromised

What are the doses and intervals of the 2024-2025 Formula COVID-19 vaccine by Moderna for people ages 12 years and older who are moderately or severely immunocompromised?

- Additional doses for people ages 12 years and older who are moderately or severely immunocompromised, which include the following:
 - A 3-dose initial series for people ages 12 years and older who are moderately or severely immunocompromised and previously unvaccinated or who need revaccination. People who need revaccination are those who are moderately or severely immunocompromised who received COVID-19 vaccine dose(s) during treatment with B-cell-depleting therapies over a limited period or who received COVID-19 vaccine dose(s) prior to or during treatment involving hematopoietic cell transplant or chimeric antigen receptor (CAR)-T-cell therapy.
 - People ages 12 years and older who are moderately or severely immunocompromised and have previously received 1 original monovalent, bivalent, or 2023-2024 Formula mRNA COVID-19 vaccine dose are recommended to receive 2 homologous (i.e., from the same manufacturer) 2024-2025 Formula mRNA vaccine doses to complete the 3-dose initial series.
 - People ages 12 years and older who are moderately or severely immunocompromised and have previously received 2 original monovalent, bivalent, or 2023-2024 Formula mRNA COVID-19 vaccine doses are recommended to receive 1 homologous 2024-2025 Formula mRNA vaccine dose, at least 4 weeks after their last COVID-19 vaccine dose.
 - For people initiating or completing the 3-dose initial series with the Moderna COVID-19 vaccine, Dose 1 and Dose 2 are recommended with a 4-week interval; Dose 2 and Dose 3 are recommended with at least a 4-week interval.
 - People ages 12 years and older who are moderately or severely immunocompromised and are previously vaccinated with an initial vaccine series may receive more than 1 dose of the 2024-2025 Formula COVID-19 vaccine by Moderna, Pfizer-BioNTech, or Novavax, informed by the clinical judgment of a healthcare provider and personal preference and circumstances.

Additional information

Refer to CDC's [Interim Clinical Considerations](#) for specific information and the latest dosing recommendations (e.g., number of doses, dosing intervals, revaccination) that may vary for individuals with certain medical conditions and/or in certain circumstances, which differ from or extend beyond the FDA-authorized and/or FDA-approved labeling.

See [Table 2](#) COVID-19 vaccination schedule for people ages 12 years and older who are moderately or severely immunocompromised in [CDC's Interim Clinical Considerations](#) for the latest dosing recommendations.

What are the formulations of the COVID-19 vaccine by Moderna that these EUI apply to?

The EUI apply to the FDA-approved 2024-2025 Formula COVID-19 vaccine by Moderna.

What are the common side effects with the COVID-19 vaccine by Moderna?

Adverse reactions that have been reported following administration of Moderna COVID-19 vaccines include injection site pain, fatigue, headache, muscle pain, chills, axillary swelling or tenderness, joint pain, nausea or vomiting, and swelling at the injection site.

What are possible serious side effects with the COVID-19 vaccine by Moderna?

Severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema), myocarditis and pericarditis have been reported following administration of Moderna COVID-19 vaccines. There is a rare risk of myocarditis and pericarditis following receipt of mRNA COVID-19 vaccine. Cases have occurred most frequently in adolescent and young adult males within 7 days after receiving the second dose of an mRNA COVID-19 vaccine (Moderna and Pfizer-BioNTech). Anaphylaxis has been rarely observed following COVID-19 vaccines. Allergic reactions can rarely occur with any kind of vaccine or medical product.

What are other clinically important side effects with the COVID-19 vaccine by Moderna?

Syncope (fainting), which may be associated with injury, may occur in association with administration of injectable vaccines, including Moderna COVID-19 vaccine.

Who should not receive the 2024-2025 Formula COVID-19 vaccine by Moderna?

Do not administer the COVID-19 vaccine by Moderna to people with known history of a severe allergic reaction (e.g., anaphylaxis) to a previous dose of mRNA COVID-19 vaccine (Moderna or Pfizer) or any component of the vaccine (see *Contraindications, and Warnings and Precautions* sections in the [Spikevax package insert](#) as well as CDC's [Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States](#) for additional considerations).

What information should be provided to persons receiving additional doses of the 2024-2025 Formula COVID-19 vaccine by Moderna as described in the EUI?

Provide the [EUI Fact Sheet for Recipients and Caregivers](#).

Risk-Benefit of the COVID-19 vaccine by Moderna as Additional Vaccine Doses for Individuals Described in the EUI

People who are moderately or severely immunocompromised and previously unvaccinated or in need of revaccination would be less likely to have protection from infection-induced immunity and thus the data supporting a single dose for those with evidence of pre-existing infection-induced immunity would be less applicable to this population. Therefore, the following evidence supports continuing a 3-dose initial series to ensure the optimal immune response to protect this population at high risk of severe outcomes with COVID-19 and the need for additional 2024-2025 Formula COVID-19 vaccine doses in people who are moderately to severely immunocompromised and previously vaccinated with an initial vaccine series. The original Pfizer-BioNTech and Moderna COVID-19 vaccine randomized controlled trials from 2020 measured efficacy of a 2-

dose initial series (previously called the primary series) among people without evidence of prior SARS-CoV-2 infection. Effectiveness of an additional primary series dose of the COVID-19 vaccine is inferred from immunogenicity data in immunocompromised adults who received a single additional primary series dose. These data were used to support EUA amendments on August 12, 2021, for the Moderna original monovalent vaccine and support the CDC recommendations to expand the primary series for persons who are moderately or severely immunocompromised to 3 doses for mRNA vaccines in August 2021. Persons who are moderately or severely immunocompromised may have reduced protection after COVID-19 vaccination, compared with persons without immunocompromise. Historically, COVID-19 vaccine effectiveness has been lower and waned more quickly for adults with immunocompromise compared to adults without immunocompromise.

For data regarding safety, please see sections in the [Spikevax package insert](#). Based on available information, it appears reasonable to anticipate that known and potential risks of additional doses of the COVID-19 vaccine by Moderna may be outweighed by its likely benefit to enhance or restore protection, which might have waned over time, especially in people who are moderately or severely immunocompromised.

Refer to the CDC's [Interim Clinical Considerations for Use of COVID-19 Vaccines](#) for additional information.

Available Alternatives

Currently, the Moderna COVID-19 vaccine and Pfizer-BioNTech COVID-19 vaccine are the FDA-approved vaccines for which EUI provide for additional dose administration to people who are moderately or severely immunocompromised. The 2024-2025 Formula Novavax COVID-19 vaccine is also available under EUA for individuals 12 years of age and older ([Novavax EUA Fact Sheet](#)). See the Interim Clinical Considerations for recommendations regarding the use of Novavax COVID-19 vaccine for persons who are moderately or severely immunocompromised

Reporting Adverse Event or Medication Errors

For Moderna (Spikevax³), approved for use in persons aged 12 years and older, healthcare providers are strongly encouraged to report the following to the Vaccine Adverse Event Reporting System (VAERS):

- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether or not it is clear that a vaccine caused the adverse event
- Vaccine administration errors, whether or not associated with an adverse event

Complete and submit reports to VAERS online at <https://vaers.hhs.gov/reportevent.html>.

For information about reporting requirements for COVID-19 vaccines under an Emergency Use Authorization (EUA), see <https://vaers.hhs.gov/reportevent.html>. For further assistance with reporting to VAERS call 1-800-822-7967.

References

Food and Drug Administration. [Package Insert - SPIKEVAX \(fda.gov\)](#)

Food and Drug Administration. FDA briefing document: [Selection of the 2024-2025 Formula for COVID-19 vaccines](#). Presented at the Vaccines and Related Biological Products Advisory Committee meeting, MD; June 5, 2024 <https://www.fda.gov/media/169378/download> [Vaccines and Related Biological Products Advisory Committee June 5, 2024 Meeting Briefing Document- FDA](#)

CDC. Science Brief: SARS-CoV-2 infection-induced and vaccine-induced immunity. 2021. <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/vaccine-induced-immunity.html>

³ Spikevax is the proprietary name for the product licensed under the Biologics License Application (BLA). Because Spikevax may be commonly referred to as the "Moderna COVID-19 Vaccine," these EUI refer to this vaccine as the COVID-19 vaccine by Moderna. Moderna COVID-19 Vaccine EUI Healthcare Providers Fact Sheet, ver 8/30/2024; originally CDC-issued 2/11/2022; prior revisions in 2022 (2/22, 3/29, 5/20, 6/24, 9/02); 2023 (9/12, 10/6); 2024 (2/29, 8/23)

Polack FP, Thomas SJ, Kitchin N, et al; C4591001 Clinical Trial Group. Safety and efficacy of the BNT162b2 mRNA COVID-19 vaccine. *N Engl J Med.* 2020;383(27):2603-2615. doi:10.1056/NEJMoa2034577

Baden LR, El Sahly HM, Essink B, Kotloff K, Frey S, Novak R, Diemert D, Spector SA, Rouphael N, Creech CB, McGettigan J, Khetan S, Segall N, Solis J, Brosz A, Fierro C, Schwartz H, Neuzil K, Corey L, Gilbert P, Janes H, Follmann D, Marovich M, Mascola J, Polakowski L, Ledgerwood J, Graham BS, Bennett H, Pajon R, Knightly C, Leav B, Deng W, Zhou H, Han S, Ivarsson M, Miller J, Zaks T; COVE Study Group. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. *N Engl J Med.* 2021 Feb 4;384(5):403-416. doi: 10.1056/NEJMoa2035389. Epub 2020 Dec 30. PMID: 33378609; PMCID: PMC7787219.

Hall VG, Ferreira VH, Ku T, Ierullo M, Majchrzak-Kita B, Chaparro C, Selzner N, Schiff J, McDonald M, Tomlinson G, Kulasingam V, Kumar D, Humar A. Randomized Trial of a Third Dose of mRNA-1273 Vaccine in Transplant Recipients. *N Engl J Med.* 2021 Sep 23;385(13):1244-1246. doi: 10.1056/NEJMc2111462. Epub 2021 Aug 11. PMID: 34379917; PMCID: PMC8385563.

Kamar N, Abravanel F, Marion O, Couat C, Izopet J, Del Bello A. Three Doses of an mRNA Covid-19 Vaccine in Solid-Organ Transplant Recipients. *N Engl J Med.* 2021 Aug 12;385(7):661-662. doi: 10.1056/NEJMc2108861. Epub 2021 Jun 23. PMID: 34161700; PMCID: PMC8262620.

Food and Drug Administration. Fact sheet for healthcare providers administering vaccine: emergency use authorization of Moderna COVID-19 vaccine (2024–2025 Formula). Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2024.
<https://www.fda.gov/media/167208/download?attachment>

Food and Drug Administration. Fact sheet for healthcare providers administering vaccine: emergency use authorization of Pfizer-BioNTech COVID-19 vaccine (2024–2025 Formula). Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2024.
<https://www.fda.gov/media/167211/download?attachment>

Food and Drug Administration. Fact sheet for healthcare providers administering vaccine: emergency use authorization of Novavax COVID-19 vaccine (2024–2025 Formula). Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2024.
<https://www.fda.gov/media/159898/download?attachment>

Link-Gelles R. Updates to COVID-19 vaccine effectiveness (VE) in the U.S. Atlanta, GA: US Department of Health and Human Services, CDC; 2023. <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-09-12/05-COVID-Link-Gelles-508.pdf>

Link-Gelles R. Effectiveness of COVID-19 (2023-2024 Formula) vaccines. Atlanta, GA: US Department of Health and Human Services, CDC; 2024. <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-06-26-28/03-COVID-Link-Gelles-508.pdf>