



Clinical Considerations for the use of 2024-2025 COVID-19 Vaccines in the United States

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Current 2024-2025 COVID-19 vaccine recommendations

- On June 27, 2024, ACIP recommended 2024-2025 COVID-19 vaccination for everyone ages 6 months and older
- On August 22, 2024, FDA approved and authorized Moderna and Pfizer-BioNTech 2024-2025 COVID-19 vaccines
- On August 30, 2024, FDA authorized Novavax 2024-2025 COVID-19 vaccine
- The [Interim Clinical Considerations for Use of COVID-19 vaccines](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html) webpage was updated with detailed recommendations
- A [Policy Note](https://www.cdc.gov/mmwr/volumes/73/wr/mm7337e2.htm) outlining the recommendations was published in the MMWR on September 10, 2024

Outline

- Use of 2024-2025 COVID-19 vaccine: **Routine schedule**
 - **Proposed** recommendations for a second dose in adults ages 65 years and older
- Use of 2024-2025 COVID-19 vaccine: **People with moderate or severe immunocompromise**
 - **Proposed** recommendations for use of additional dose(s) in people with moderate or severe immunocompromise
- Updates to clinical considerations

Routine schedule

People *without* moderate or severe immunocompromise

Current recommendations for children ages 6 months – 4 years

Doses recommended:

- Initial series of 2 Moderna vaccine doses OR 3 Pfizer-BioNTech vaccine doses
- **At least 1 dose of 2024–2025 COVID-19 vaccine, as part of or in addition to initial series**

- All doses should be homologous (i.e., from the same manufacturer)

Current recommendations for people ages 5 years and older

Doses recommended:

- 1 dose of 2024-2025 COVID-19 vaccine

- 2024–2025 COVID-19 vaccine dose is recommended at least 2 months after receipt of the last COVID-19 vaccine dose
- mRNA COVID-19 vaccines authorized or approved for ages 6 months and older and Novavax COVID-19 vaccine authorized for ages 12 years and older
- People who are previously unvaccinated for COVID-19 and are receiving Novavax should complete a 2-dose initial series

Proposed recommendations for people ages 5 – 64 years

Doses recommended:

- 1 dose of 2024-2025 COVID-19 vaccine

- 2024–2025 COVID-19 vaccine dose is recommended at least 2 months after receipt of the last COVID-19 vaccine dose
- mRNA COVID-19 vaccines authorized or approved for ages 6 months and older and Novavax COVID-19 vaccine authorized for ages 12 years and older
- People who are previously unvaccinated for COVID-19 and are receiving Novavax should complete a 2-dose initial series

Proposed recommendations for adults ages 65 years and older

Doses recommended:

- 2 doses of 2024-2025 COVID-19 vaccine
 - Recommended interval 6 months (minimum interval 2 months)

- If previously unvaccinated and receiving Novavax, 2 doses are recommended as initial vaccination series followed by a third dose of any age-appropriate 2024-2025 COVID-19 vaccine 6 months (minimum interval 2 months) after second dose.

**Recommendations for people with
moderate or severe immunocompromise**

Current recommendations for people ages 6 months and older who are moderately or severely immunocompromised

Doses recommended:

- Initial COVID-19 vaccine series*
- **At least 1 2024–2025 COVID-19 vaccine dose**
- May receive 1 additional 2024-2025 COVID-19 vaccine dose with option for further additional doses of 2024-2025 COVID-19 vaccine**

*Series of 3 homologous mRNA COVID-19 vaccine doses or 2 Novavax COVID-19 vaccine doses (if ages 12 years and older); includes revaccination after hematopoietic cell transplant and CAR-T-cell, or B-cell-depleting therapies.

**Further additional dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Further additional doses should be administered at least 2 months after the last 2024-2025 COVID-19 vaccine dose.

For more information, see <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised>.

Proposed recommendations for people ages 6 months and older who are moderately or severely immunocompromised

Doses recommended:

- Initial COVID-19 vaccine series*
- **At least 2 2024–2025 COVID-19 vaccine doses****
 - **Recommended interval 6 months (minimum interval 2 months)**
- Additional 2024-2025 COVID-19 vaccine doses under shared clinical decision making***

*Series of 3 homologous mRNA COVID-19 vaccine doses or 2 Novavax COVID-19 vaccine doses (if ages 12 years and older); includes revaccination after hematopoietic cell transplant and CAR-T-cell, or B-cell-depleting therapies.

**One 2024-2025 COVID-19 vaccine dose may be received as part of the initial vaccination series and at least one of the two doses should be received 6 months (minimum interval 2 months) after completion of the initial series.

***Additional doses should be administered at least 2 months after the last 2024-2025 COVID-19 vaccine dose.

For more information, see <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised>.

Updates to Clinical Considerations

Clinical considerations

- **Age transitions**
- **Interchangeability of COVID-19 vaccines**
- **COVID-19 vaccination and prior SARS-CoV-2 infection**

Transitioning from a younger to older age group

- **CDC recommends that people receive the age-appropriate vaccine product and dosage based on their age on the day of vaccination.**
- **If a person moves to an older age group between vaccine doses, they should receive the vaccine product and dosage for the older age group. For children who transition from age 4 years to age 5 years and children who are moderately or severely immunocompromised and transition from age 11 years to age 12 years, the option to administer a lower dosage is no longer authorized.**

Interim Clinical Considerations on interchangeability of COVID-19 vaccines

- **COVID-19 vaccine doses from the same manufacturer should be administered whenever recommended. In the following circumstances, an age-appropriate COVID-19 vaccine from a different manufacturer may be administered:**
 - Same vaccine not available **at the vaccination site at the time of the clinic visit**
 - Previous dose unknown
 - Person would otherwise **not receive a recommended vaccine dose**
 - Person starts but unable to complete a vaccination series with the same COVID-19 vaccine due to a contraindication
- A Vaccine Adverse Event Reporting System (VAERS) report is not indicated **in these circumstances.**

Additional guidance: Interim Clinical Considerations on interchangeability of COVID-19 vaccines – Novavax*

- **People ages 12 years and older who are initiating vaccination with Novavax COVID-19 Vaccine (i.e., previously unvaccinated) and receive a first dose of Novavax should complete the 2-dose initial vaccination series with Novavax vaccine.**
- **However, if more than 8 weeks have elapsed since receipt of the first dose of Novavax, any 2024–2025 COVID-19 vaccine (i.e., Moderna, Novavax, or Pfizer-BioNTech) may be administered.**

*For people who are not moderately or severely immunocompromised

<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#Interchangeability>

Reminder: COVID-19 vaccine and prior SARS-CoV-2 infection

- COVID-19 vaccination is recommended for everyone ages 6 months and older, regardless of prior symptomatic or asymptomatic SARS-CoV-2 infection, including people with Long COVID.
- People who recently had SARS-CoV-2 infection *may consider* delaying a COVID-19 vaccine dose by **3 months** from symptom onset or positive test (if infection was asymptomatic).
- Individual factors such as risk of severe COVID-19 and current indicators of community transmission should be taken into account when determining whether to delay getting a COVID-19 vaccination after infection.

Summary

Overview of the COVID-19 vaccination schedule:

Routine vaccination

- **Children ages 6 months–4 years**
 - Unvaccinated: Should receive a multidose initial series with a 2024–2025 mRNA vaccine
 - Previously completed an initial series: Should receive 1 dose of a 2024–2025 mRNA vaccine from the same manufacturer as the initial series
- **People ages 5–64 years:**
 - Should receive 1 dose of an age-appropriate 2024-2025 COVID-19 vaccine*
- **People ages 65 years and older:**
 - Should receive 2 doses of any 2024–2025 COVID-19 vaccine, spaced 6 months apart (minimum interval 2 months)**

*People ages 12-64 years who are unvaccinated and receive the 2024-2025 Novavax COVID-19 vaccine for initial vaccination should receive 2 doses of 2024-2025 Novavax COVID-19 vaccine.

**People ages 65 years and older who are unvaccinated and receive Novavax COVID-19 Vaccine for initial vaccination should receive 2 doses of 2024–2025 Novavax COVID-19 vaccine followed by a third dose of any 2024–2025 COVID-19 vaccine dose 6 months after the second dose (minimum interval 2 months).

Overview of the COVID-19 vaccination schedule:

Moderate or severe immunocompromise

- **Unvaccinated:**
 - Should receive a multidose vaccination series with an age-appropriate 2024–2025 vaccine and receive 1 2024–2025 dose 6 months after completing the initial series (minimum interval 2 months)
- **Previously completed an initial series:**
 - Should receive 2 doses of an age-appropriate 2024–2025 COVID-19 vaccine, spaced 6 months apart (minimum interval 2 months)
- **May receive additional age-appropriate 2024–2025 COVID-19 vaccine doses under shared clinical decision-making**

Summary

- **Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States** webpage continues to be rapidly updated to reflect the most recent COVID-19 vaccine guidance
- **COVID-19 vaccine recommendations have moved towards simplicity and the standard language used for the ACIP routine immunization schedules and General Best Practices**
- **Recommendations for use of additional doses in older adults and people with moderate or severe immunocompromise will be updated following the October 2024 ACIP meeting votes**

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

