COVID-19 Vaccine administration guidance

COVID-19 vaccine for the general population

- On Monday, August 23, 2021, the FDA granted full approval to the Pfizer-BioNTech COVID-19 vaccine. The vaccine’s two-dose regimen, 21 days apart, is approved for people aged 16 or older.
- For individuals aged 12 to 15, the Pfizer-BioNTech COVID-19 vaccine is available via emergency use authorization (EUA).
- The FDA has approved the Pfizer-BioNTech for vaccination of children aged 5-11 via an EUA.
- The Moderna two-dose regimen, 28 days apart, and J&J/Janssen single dose COVID-19 vaccines are available via EUA for people age 18 or older.
- Individuals who are moderately or severely immunocompromised may receive a third dose of the Moderna or Pfizer-BioNTech vaccine at least 28 days after the second dose under an EUA.*
- Booster doses of the Pfizer-BioNTech, Moderna, and J&J/Janssen vaccine are available.† See details below for booster dose information.

Booster Dose Information

As of October 27, all three FDA authorized vaccines have booster doses available for the public. The Pfizer-BioNTech and Moderna booster doses have specific qualifications (see details below). The J&J/Janssen vaccine only requires individuals to be 18 years or older. Additionally, a mix and match approach has been authorized; please see details below.

**Pfizer-BioNTech & Moderna‡ Booster Dose Eligibility (6 months after primary series)**

- 65 years or older
- Age 18-64 who live in long-term care settings
- Age 18-64 who have underlying medical conditions
  - Individuals with advanced skin cancer can be candidates for a booster dose
  - Individuals on immunomodulatory agents or who are immunocompromised can be candidates for a booster dose
- Age 18-64 who work or live in high-risk settings

* Individuals who are immunocompromised may not build enough protection from the standard two-dose regimen of the mRNA vaccines. It is advised they receive a third dose 28-days after the initial 2-dose mRNA vaccine regimen (Pfizer or Moderna). On the contrary, a booster dose is for individuals who built enough protection from the standard two-dose regimen, but their level of protection decreased over time.

† A booster shot is the term for fully vaccinated patients, 6 or 2 months after their initial vaccination.

‡ The Moderna booster dose is half of a single dose from the primary series.

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Healthcare workers fall under this category and can receive a booster dose

**J&J/Janssen Booster Dose Eligibility (2 months after primary series)**
- Age 18 or older

**Mix and Match approach:**
- If the individual’s primary series was either the Pfizer or Moderna vaccines, they can have a booster dose of any of the 3 FDA-authorized vaccines after six months.
- If the individual’s primary series was the Johnson and Johnson vaccine, they can have a booster dose of any of the 3 FDA-authorized vaccines after two months.
- Currently, the Johnson and Johnson booster dose is the only vaccine without a priority category. The only requirement is that the individual is 18 years or older to receive a booster dose of the Pfizer or Moderna vaccines, the individual must be eligible based on priority categories (see list above).

For a summary of the homogenous vaccination, regimen see **Table I**. For an overview on mix and match approach vaccination, see **Table II**.

**Table I. Summary of COVID-19 vaccination eligibility**

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Primary Vaccine Series</th>
<th>Booster Dose Eligibility</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1st Dose</td>
<td>2nd Dose</td>
</tr>
<tr>
<td>Pfizer</td>
<td>Yes</td>
<td>Yes (After 21 days)</td>
</tr>
<tr>
<td></td>
<td>Age 5+</td>
<td></td>
</tr>
<tr>
<td>Moderna</td>
<td>Yes</td>
<td>Yes (After 28 days)</td>
</tr>
<tr>
<td></td>
<td>Age 18+</td>
<td></td>
</tr>
<tr>
<td>J&amp;J</td>
<td>Yes</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Age 18+</td>
<td></td>
</tr>
</tbody>
</table>

§ In the case of individuals who are immunocompromised and received the Pfizer-BioNTech or Moderna as their primary vaccine series the booster dose would be their 4th COVID-19 vaccine dose. In the case of individuals who are immunocompromised and received the J&J/Janssen as their primary vaccine series the booster dose would be their 2nd COVID-19 vaccine dose.
COVID-19 vaccine in the workplace

On September 9, the Biden administration shared its COVID-19 Plan. The Plan mentions that the Department of Labor’s Occupational Safety and Health Administration (OSHA) is developing a rule to require employers to ensure their workforce is vaccinated. This rule will be implemented via an Emergency Temporary Standard (ETS) and applies to employers with 100+ employees. Additionally, employees who are not vaccinated will have to show proof of weekly negative COVID-19 tests.

All federal executive branch workers and contractors who do business with the federal government will be required to be vaccinated. This mandate will be implemented via executive order by the Department of Defense, the Department of Veteran Affairs, the Indian Health Service, and the National Institute of Health. The Centers for Medicare and Medicaid Services (CMS) will require COVID-19 vaccinations for workers in healthcare facilities that receive Medicare and/or Medicaid reimbursement. This requirement will include, but may not be limited to, hospitals, dialysis facilities, ambulatory surgery centers, and home health agencies. It is not clear if this mandate will cover physician offices.

Overall, these new COVID-19 vaccine policies will affect both the private and public sectors. Additionally, individual states may develop their own more stringent COVID-19 vaccination policies. Therefore, becoming familiar with your state’s policy will be important.

Check www.aad.org/coronavirus for updates as these mandates are rolled out.

Contraindications for COVID-19 vaccine

CDC considers a history of the following to be a contraindication to vaccination with COVID-19 vaccines:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
- Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine
  - Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema,
respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

Appendix B: Triage of people presenting for COVID-19 vaccination

<table>
<thead>
<tr>
<th>CONTRAINDICATION TO VACCINATION</th>
<th>PRECAUTION TO VACCINATION</th>
<th>MAY PROCEED WITH VACCINATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of the following:</td>
<td>Among people without a contraindication, a history of:</td>
<td>Among people without a contraindication or precaution, a history of:</td>
</tr>
<tr>
<td>• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine†</td>
<td>• Any immediate allergic reaction* to other vaccines or injectable therapies‡</td>
<td>• Allergy to oral medications (including the oral equivalent of an injectable medication)</td>
</tr>
<tr>
<td>• Immediate allergic reaction+ of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine+</td>
<td>Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa. See footnote for additional information on additional measures to take in these people.*</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• History of food, pet, insect, venom, environmental, latex, etc., allergies</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Family history of allergies</td>
</tr>
</tbody>
</table>

Actions:
- Do not vaccinate.
- Consider referral to allergist-immunologist.
- Consider other vaccine alternative.*

Actions:
- Risk assessment
- Consider referral to allergist-immunologist
- 30-minute observation period if vaccinated

Actions:
- 30-minute observation period; people with history of anaphylaxis (due to any cause)
- 15-minute observation period; all other people

† See Appendix C for a list of ingredients. People with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna).

* Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

‡Includes people with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but in whom it is unknown which component elicited the immediate allergic reaction.

#Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur. People with a contraindication to mRNA COVID-19 vaccines (including due to a known allergy to PEG) have a precaution to Janssen COVID-19 vaccine. Among people who received one mRNA COVID-19 dose but for whom the second dose is contraindicated, consideration may be given to vaccination with Janssen COVID-19 vaccine (administered at least 28 days after the mRNA COVID-19 dose). People with a contraindication to Janssen COVID-19 vaccine (including due to a known allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines. For people with these precautions, referral to an allergist-immunologist should be considered. Healthcare providers and health departments may also request a
consultation from the Clinical Immunization Safety Assessment COVIDvax project. In patients with these precautions, vaccination should only be undertaken in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

Table Source: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-B

Recommendations for COVID-19 vaccinated persons

Fully vaccinated people can resume activities without wearing a mask or physically distancing, except where required by federal, state, local, tribal, or territorial laws, rules, and regulations, including local business and workplace guidance.

Vaccinated persons can avoid quarantine post-exposure to someone with suspected or confirmed COVID-19 if the following criteria are met:

- Are fully vaccinated (i.e., ≥2 weeks following receipt of the second dose in a 2-dose series, or ≥2 weeks following receipt of one dose of a single-dose vaccine)
- Previously diagnosed with COVID-19 within the last 3 months and has not developed any new symptoms.

If all the criteria mentioned above are not met, people should continue to follow current quarantine guidance after exposure to someone with suspected or confirmed COVID-19. For more information, please see the latest CDC guidance.

Fully vaccinated persons should still watch for symptoms of COVID-19, especially if they are around someone sick. If they experience symptoms, they should be clinically evaluated for COVID-19, including SARS-CoV-2 testing, if indicated. In addition, vaccinated persons should continue to follow current guidance to protect themselves and others, including all other SARS-CoV-2 testing recommendations and requirements and state, territorial, tribal, and local travel recommendations or requirements. For additional considerations regarding quarantine or work restrictions for fully vaccinated healthcare personnel, patients, or residents in healthcare settings, please see the section below.

This guidance applies to COVID-19 vaccines currently authorized for emergency use by the U.S. Food and Drug Administration: Pfizer-BioNTech, Moderna, and Johnson and Johnson (J&J)/Janssen COVID-19 vaccines. As well as those fully approved by the FDA (Pfizer BioNTech COVID-19 vaccine). This guidance can also be applied to COVID-19 vaccines that have been authorized for emergency use by the World Health Organization (e.g., AstraZeneca/Oxford).

COVID-19 vaccine for people with facial fillers

Two of the participants in clinical trials for Moderna’s COVID-19 vaccine who had received dermal filler injections in the cheeks were reported to have developed facial swelling after receiving the vaccination. One subject had filler injections two weeks prior to the vaccination and the other 6 months prior. A third person, who had had a history of lip injection, reportedly developed lip
angioedema two days after receiving the vaccination. This participant reported a similar reaction in the past following influenza vaccination.

The localized swelling resolved itself after treatment with antihistamines or steroids in all three cases. The majority of trial participants experienced only mild side effects typical with vaccines, including headache, fatigue, and pain at the injection site. In its report on the Moderna vaccine hearing, the FDA notes that "it is possible the localized swelling in these cases is due to an inflammatory reaction from the interaction between the immune response after vaccination and the dermal filler."

Although the data is limited, having a history of fillers should NOT prevent you from getting the COVID 19 vaccine considering the limited risks vs. benefits.

To read detailed information on the Pfizer and Moderna vaccine trial, click the links

- FDA Pfizer Trial Summary
- FDA Moderna Trial Summary
- FDA Janssen Trial Summary

Reporting of vaccine adverse events

Currently, the AAD COVID-Derm registry is set up to receive dermatologic manifestations of the booster (third shot), and they should be reported to the registry in the same manner manifestations of COVID infection, and initial immunization have been reported. [COVID-19 Dermatology Registry]

Additional Resources on COVID 19 vaccine administration guidance from other medical societies:

3) NPF key recommendations for the management of patients with psoriatic disease during the COVID-19 pandemic: https://www.psoriasis.org/covid-19-task-force-guidance-statements/