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 is approved for people aged 16 or older. For individuals aged 12 to 15, the vaccine is available via emergency use authorization (EUA). Similarly, for individuals who are immunocompromised and may require a third dose, the Pfizer-BioNTech vaccine is available via EUA (See details below for third dose information). Both the Moderna and the J&J/Janssen COVID-19 vaccines are available via EUA for people age 18 or older.

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 physician offices will be covered by this mandate.

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.

COVID-19 vaccine for patients on immunomodulatory agents

The CDC advises that immunocompromised individuals may receive COVID-19 vaccination if they have no contraindications* to vaccination. Immunocompromised patients due to an underlying
immunodeficiency or medication-induced, may benefit from a 3rd dose of mRNA COVID-19 vaccine as they seem to have a less robust antibody response to the initial vaccine series.

The FDA amended the emergency use authorization (EUA) for the Pfizer-BioNTech and Moderna COVID-19 vaccines by allowing additional doses in certain immunocompromised individuals. The [CDC now recommends](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/third-dose.html) people who are moderately to severely immunocompromised should receive an additional dose of their original mRNA COVID-19 vaccine at least four weeks (28 days) after the initial 2 doses. This additional dose may increase protection against COVID-19 infection in this population. Currently, the Moderna vaccine has EUA for people ≥18 years, and the Pfizer-BioNTech vaccine has EUA for people 12-15 years. The Pfizer-BioNTech vaccine has full FDA approval for individuals 16 or older. Guidance on 3rd doses in general for all vaccinated individuals 8 months after the second dose of mRNA vaccines is forthcoming.

The FDA also encourages immunocompromised individuals to discuss monoclonal antibody [treatment options](https://www.fda.gov/Coronavirus-Update/COVID-19-vaccines) with their healthcare provider if they contract or are exposed to COVID-19. This is due to the risk of the infection progressing to severe COVID-19 and/or leading to possible hospitalization. This treatment is not a substitute for COVID-19 vaccination. For detailed information please click [FDA guidance for immunocompromised individuals](https://www.fda.gov/Coronavirus-Update/COVID-19-vaccines).

Shared decision making should be made between the patients and clinicians to guide discussions about the use of oral-systemic and biologic agents during the pandemic. To review the Academy’s guidance on the use of immunosuppressive agents during the pandemic review [Guidance on the use of immunosuppressive agents](https://www.aan.com/practice/guidelines/immunosuppression).

**Contraindications**

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
† 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 health care 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](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 have not developed any new symptoms.

If all the above-mentioned criteria 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 with 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 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:

1) 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/


