

COVID Vaccine Information

Key attributes of the COVID vaccines which have received Emergency Use Authorization (EUA) from the Food and Drug Administration

	Moderna	Pfizer/BioNTech
# of doses	2	2
# of days between doses (if applicable)	28	21
Dosage amount	100 μg	30 μg
Lower age bound of EUA	18	16
Product type	mRNA/liquid nanoparticle	mRNA/liquid nanoparticle
Dilution required	No	Yes
Temperature requirements	Stable for 12 hours at room temperature	Stored around -75°C
Population size	~30,000	>43,000
Timing of BLA		Expected Spring 2021
Emergency Use Authorization	December 18	December 11
FDA Fact sheets	<u>Here</u>	Here
CDC Interim clinical considerations	<u>Here</u>	Here
CDC FAQs	<u>Here</u>	Here
ACIP recommendations	<u>Here</u>	Here
Other CDC resources	<u>Here</u>	Here
Fetal cells used in development of vaccine ¹	No	No

Some vials of the Pfizer-BioNTech COVID-19 vaccine have contained extra product after five doses is obtained. Can the extra be used? — Answer: The Food and Drug Administration (FDA) is aware of the issue and is working with Pfizer to determine the best path forward and will share additional updates as we have them. At this time, given the public health emergency, FDA is advising that it is acceptable to use every full dose obtainable (the sixth, or possibly even a seventh) from each vial, pending resolution of the issue. However, since the vials are preservative free, it is critical to note that any further remaining product that does not constitute a full dose should not be pooled from multiple vials to create one. Source: Pfizer-BioNTech COVID-19 Vaccine Frequently Asked Questions

EEOC Publishes COVID-19 Vaccine Guidance

The Equal Employment Opportunity Commission says employers can require employees to get a COVID-19 vaccine. Guidance published by the agency states that mandatory vaccination programs are permitted as long as employers follow Americans with Disabilities Act and Title VII accommodation requirements. Read more.

¹ For more information on this topic, note the <u>statement</u> by the US Conference of Bishops and this explanatory <u>article</u>.

Religious Vaccine Objections to Clash With Employer Defense: Workers seeking religious exemptions from Covid-19 vaccine mandates must overcome the U.S. Supreme Court's employer-friendly precedent that allows businesses to reject those requests if they're too burdensome. Employers need only show that the requested religious accommodation would cause more than a trivial cost to their operations, under the high court's 1977 ruling in IWA v. Hardison. That "undue hardship" standard has been criticized as too low by academics, religious groups, the U.S. Justice Department, and some federal judges.

On December 17, the Centers for Medicare & Medicaid Services (CMS) released a **new update to the** *Coverage and Reimbursement of COVID-19 Vaccines, Vaccine Administration and Cost Sharing under Medicaid, the Children's Health Insurance Program, and Basic Health Program Toolkit* that was originally released on October 28th and first updated on November 23rd. This update includes additional information regarding vaccine administration reimbursement and outlines a streamlined review process available to states looking to expeditiously adjust vaccine administration reimbursement rates in their state plan. We have also updated the toolkit with further clarification regarding managed care network adequacy and the phased distribution and administration of the Pfizer-BioNTech and other EUA approved COVID-19 vaccines.

• Updated COVID-19 Vaccine Toolkit

COVID-19 Vaccination — The <u>COVID-19 vaccination website</u> has been updated to provide clinical resources for each COVID-19 vaccine, including information for COVID-19 vaccination administration, storage and handing, reporting, and patient education.

Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites — Anaphylaxis is an acute and potentially life-threatening serious allergic reaction. These clinical considerations provide information on preparing for the initial assessment and management of anaphylaxis following COVID-19 vaccination.

Post Vaccine Considerations for Healthcare Personnel — Strategies are needed for healthcare facilities to appropriately evaluate and manage post-vaccination signs and symptoms among healthcare personnel. <u>These considerations</u> are based on the current understanding of signs and symptoms following COVID-19 vaccination, including timing and duration, and might change as experience with the vaccine accumulates.

COVID-19 Vaccination Communication Toolkit — Medical centers, clinics, and clinicians can use or adapt <u>these</u> <u>ready-made materials</u> to build confidence about COVID-19 vaccination among healthcare teams and staff. This toolkit also provides resources that can be used to educate patients and answer questions about the vaccines.

COVID-19 Vaccine EUA Fact Sheets for Recipients and Caregivers — For each COVID-19 vaccine authorized under an Emergency Use Authorization (EUA), the Food and Drug Administration (FDA) requires that vaccine recipients or their caregivers are provided with certain vaccine-specific EUA information to help make an informed decision about vaccination. To learn more, please visit: <u>Vaccines & Immunizations</u>

Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine— On December 12, 2020, the Advisory Committee on Immunization Practices issued an interim recommendation for use of the Pfizer-BioNTech COVID-19 vaccine for the prevention of COVID-19 in persons aged 16 years and older. The Pfizer-BioNTech COVID-19 vaccine is a lipid nanoparticle-formulated, nucleoside-modified mRNA vaccine encoding the prefusion spike glycoprotein of SARS-CoV-2, the virus that causes COVID-19. To learn more, please visit: Vaccines & Immunizations.

Local Reactions, Systemic Reactions, Adverse Events, and Serious Adverse Events: Pfizer-BioNTech COVID-19 Vaccine — Among all study vaccine recipients asked to complete diaries of their symptoms during the 7 days after vaccination, 84.7% reported at least one local injection site reaction. By age group, 88.7% in the younger group (aged 18 to 55 years) and 79.7% in the older group (aged >55 years) reported at least one local reaction. To learn more, please visit: Local Reactions.

Pfizer-BioNTech COVID-19 Vaccine — The new <u>Pfizer-BioNTech COVID-19 Vaccine webpage</u> has information specific to Pfizer's vaccine, including resources to assist providers in storing, handling, and administering the vaccine.

V-safe After Vaccination Health Checker - Healthcare systems and providers have a vital role in encouraging COVID-19 vaccine recipients to participate; please see recommended provider/patient script below. In addition, CDC's <u>v-safe web pages</u>provide information on how to register and complete a <u>v-safe</u> health check-in (including step-by-instructions with images), troubleshooting, FAQs, and contact information for technical support. These web pages will be continuously updated with additional resources. Suggested healthcare provider script for encouraging patients to participate in <u>v-safe</u>:

CDC has created a way for you to report how you feel after COVID-19 vaccination through a smartphone-based tool that uses text messaging and web surveys to check in with you. Here (or in your packet) is a **v-safe** information sheet with more details and simple instructions to sign up.

U.S. COVID-19 Vaccine Product Information — Find a suite of <u>information and materials</u> that are needed for each specific COVID-19 vaccine that cover administration, storage and handling, safety, and reporting.

Different COVID-19 Vaccines — As COVID-19 vaccines are authorized and then recommended for use in the United States, it will be important to understand what is known about each vaccine. To learn more, please visit: <u>Different Vaccines</u>

Report an Adverse Event to VAERS — The <u>Vaccine Adverse Event Reporting System (VAERS)</u> is a passive reporting system, meaning it relies on individuals to send in reports of their experiences. Anyone can submit a report to VAERS, including parents and patients.

COVID-19 Science Update — To help inform CDC's COVID-19 Response, as well as to help CDC staff stay up to date on the latest COVID-19 research, the Response's Office of the Chief Medical Officer has collaborated with the CDC Office of Library Science to create a series called COVID-19 Science Update.

The Centers for Disease Control and Prevention will provide weekly updates on allocations of the Pfizer and Moderna COVID-19 vaccines to state and tribal jurisdictions. This dataset lists the allocations of doses made available for states and jurisdictions to order against. Weekly allocations are provided to states on Tuesdays; after doses are ordered by states, shipments begin the following Monday. The entire order may not arrive in one shipment or on one day, but over the course of the week; delivery sites are notified by the private shipping partners. Shipments of an FDA-authorized safe and effective COVID-19 vaccine continue to arrive at sites across America. Vaccinations began on December 14, 2020.

Resources for Health Care Workers Administering Vaccines

Health care workers who are exposed to needles, for example, while administering vaccines, are at risk of sharps injury and exposure to bloodborne pathogens. NIOSH and our partners have many resources on how to keep health care workers safe. This includes information on how to <u>reduce sharps injuries</u> and what to do if you have a <u>sharps injury</u>.

CDC/NIOSH Resources

- Ensuring the Proper PPE when Administering COVID-19 Vaccine
- Preparing Your Practice for COVID-19 Vaccination
- Preventing Needlesticks in Health Care Settings (Also Available in Spanish)
- Preventing Needlesticks and Sharps Injuries
- Stop Sticks Campaign
- What Every Worker Should Know: How to Protect Yourself From Needlestick Injuries (Also Available in Spanish)

OSHA Resources

- Bloodborne Pathogens and Needlestick Prevention
- Healthcare Wide Hazards Needlestick/Sharps Injuries

The CDC published several materials to help individuals navigate the COVID-19 vaccination process: What to Expect at Your Appointment to Get Vaccinated for COVID-19, What to Expect After Getting a COVID-19 Vaccine, Post-Vaccine Considerations for Residents of Long-Term Care Facilities, and Post-Vaccine Considerations for Healthcare Personnel.

Other CDC Resources

- Recipient education, including making a strong recommendation, answering questions, and understanding and explaining mRNA vaccines
- Planning and partnerships
- Vaccination toolkits