COVID Vaccine Information

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

<table>
<thead>
<tr>
<th></th>
<th>Moderna</th>
<th>Pfizer/BioNTech</th>
</tr>
</thead>
<tbody>
<tr>
<td># of doses</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td># of days between doses (if applicable)</td>
<td>28</td>
<td>21</td>
</tr>
<tr>
<td>Dosage amount</td>
<td>100 µg</td>
<td>30 µg</td>
</tr>
<tr>
<td>Lower age bound of EUA</td>
<td>18</td>
<td>16</td>
</tr>
<tr>
<td>Product type</td>
<td>mRNA/liquid nanoparticle</td>
<td>mRNA/liquid nanoparticle</td>
</tr>
<tr>
<td>Dilution required</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Temperature requirements</td>
<td>Stable for 12 hours at room temperature</td>
<td>Stored around -75°C</td>
</tr>
<tr>
<td>Population size</td>
<td>~30,000</td>
<td>&gt;43,000</td>
</tr>
<tr>
<td>Timing of BLA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FDA Fact sheets</td>
<td>Here</td>
<td>Here</td>
</tr>
<tr>
<td>CDC Interim clinical considerations</td>
<td>Here</td>
<td>Here</td>
</tr>
<tr>
<td>CDC FAQs</td>
<td>Here</td>
<td>Here</td>
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<tr>
<td>ACIP recommendations</td>
<td>Here</td>
<td>Here</td>
</tr>
<tr>
<td>Other CDC resources</td>
<td>Here</td>
<td>Here</td>
</tr>
<tr>
<td>Fetal cells used in development of vaccine¹</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

**Updated** Frequently Asked Questions: Facts about COVID-19 Vaccines — Now that there are authorized and recommended COVID-19 vaccines in the United States, accurate vaccine information is critical. See Facts about COVID-19 Vaccines.

This report summarizes the clinical and epidemiologic characteristics of case reports of allergic reactions, including anaphylaxis and nonanaphylaxis allergic reactions, after receipt of the first dose of Moderna COVID-19 vaccine during December 21, 2020–January 10, 2021, in the United States. CDC has issued updated interim clinical considerations for use of mRNA COVID-19 vaccines currently authorized in the United States and interim considerations for preparing for the potential management of anaphylaxis...

**New** USP COVID-19 Vaccine Handling Toolkit: Operational Considerations for Healthcare Practitioners

¹ For more information on this topic, note the statement by the US Conference of Bishops and this explanatory article.
New NIOSH COVID-19 Vaccine Communication Toolkit for Essential Workers
A new communication toolkit is available to help employers build confidence in their workforce for this important new vaccine. The toolkit will help employers across various industries provide information about COVID-19 vaccines, increase awareness about vaccination benefits, and address common questions and concerns. The toolkit contains a variety of resources including key messages, FAQs, posters, newsletter content, and more. Partners are encouraged to adapt the key messages to the language, tone, and format that will resonate with the organizations and industries they serve.

This report summarizes the clinical and epidemiologic characteristics of case reports of allergic reactions, including anaphylaxis and nonanaphylaxis allergic reactions, after receipt of the first dose of Pfizer-BioNTech COVID-19 vaccine during December 14–23, 2020, in the United States.

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 (EEOC) says employers can require employees to get a COVID-19 vaccine. Guidance published by the agency, and updated in January 2021, states that mandatory vaccination programs are permitted as long as employers follow Americans with Disabilities Act and Title VII accommodation requirements. Read more.

In response to inquiries from the public, the EEOC has provided resources on its website related to the pandemic in an employment context. The agency will continue to monitor developments and provide assistance to the public as needed.

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 TWA 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 [COVID-19 vaccination website](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/other-vaccines.html) has been updated to provide clinical resources for each COVID-19 vaccine, including information for COVID-19 vaccination administration, storage and handling, reporting, and patient education.

**CDC COVID Data Tracker** — Vaccinations are now being tracked on [CDC’s COVID Data Tracker](https://covid WONDER.cdc.gov/covidwonder.html). Numbers reported on CDC’s website are validated through a submission process with each jurisdiction and may differ from numbers posted on other websites. Differences between reporting jurisdictions and CDC’s website may occur due to the timing of reporting and website updates.

**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](https://www.cdc.gov/vaccines/interim-guidance/potential-management-anaphylaxis-covid-19-vaccine.html) 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. [These considerations](https://www.cdc.gov/vaccines/interim-guidance/post-vaccine-considerations.html) 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 [these ready-made materials](https://www.cdc.gov/vaccines/interim-guidance/communication-toolkit.html) 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: [Vaccines & Immunizations](https://www.cdc.gov/vaccines/interim-guidance/eua-fact-sheets.html).

**Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States** — This guidance has been updated to include the following:

- Additional information on antibody therapies and COVID-19 vaccination
- Information on COVID-19 vaccination and outbreak management
- Additional information on vaccination of immunocompromised persons
- Updates to contraindications and precautions to vaccination
- Information on COVID-19 vaccination and tuberculin skin testing

To learn more, please visit: [mRNA COVID-19 Vaccines](https://www.cdc.gov/vaccines/interim-guidance/mrna-covid-19-vaccines.html).

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 Pfizer-BioNTech COVID-19 Vaccine webpage 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 v-safe web pages provide information on how to register and complete a v-safe 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 v-safe:

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 information and materials 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: Different Vaccines

How to Report COVID Vaccine-Related Adverse Events — As Americans start receiving their first COVID-19 vaccines, additional data on potential adverse events are needed in real time. Healthcare providers will play a critical role in reporting vaccine-related adverse events through the Vaccine Adverse Event Reporting System (VAERS). Providers can also encourage individual patients to self-report potential adverse events as they occur through v-safe, CDC’s new patient reporting platform. Read more in this new CDC Medscape Expert Commentary by Dr. Tom Shimabukuro, CDC’s COVID-19 Vaccine Safety Team Lead.

Report an Adverse Event to VAERS — The Vaccine Adverse Event Reporting System (VAERS) 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.

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 reduce sharps injuries and what to do if you have a sharps injury.

CDC/NIOSH Resources

Prepared by Hart Health Strategies Inc., 01/28/2021
• 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

People with Certain Medical Conditions — Revisions were made on December 23, 2020 to reflect recent data supporting increased risk of severe illness among persons with Down Syndrome from the virus that causes COVID-19. Revisions also include addition of sickle cell disease and chronic kidney disease to the conditions that might increase the risk of severe illness among children.