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>
<th>J&amp;J/Janssen</th>
</tr>
</thead>
<tbody>
<tr>
<td># of doses</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td># of days between doses (if applicable)</td>
<td>28</td>
<td>21</td>
<td>n/a</td>
</tr>
<tr>
<td>Lower age bound of EUA</td>
<td>18</td>
<td>16</td>
<td>18</td>
</tr>
<tr>
<td>Product type</td>
<td>mRNA/liquid nanoparticle</td>
<td>mRNA/liquid nanoparticle</td>
<td>DNA/adenovirus (viral vector)</td>
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<tr>
<td>Dilution required</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Timing of BLA</td>
<td>Use Emergency Authorization</td>
<td>December 18</td>
<td>Expected Spring 2021</td>
</tr>
<tr>
<td>FDA Fact sheets</td>
<td>Here</td>
<td>Here</td>
<td>Here</td>
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<tr>
<td>CDC Interim clinical considerations</td>
<td>Here</td>
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<tr>
<td>CDC FAQs</td>
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<td>ACIP recommendations</td>
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<tr>
<td>Other CDC resources</td>
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</tbody>
</table>

NEW CDC: CDC Real-World Study Confirms Protective Benefits of mRNA COVID-19 Vaccines

NEW Learn More About COVID-19 Vaccines From the FDA.

NEW CDC has designed a new mini-webinar series addressing different topics related to COVID-19 vaccination. Each webinar is approximately 15 minutes and offers CE. CDC’s first two webinars are available through the Training and Education Webinar Resources webpage, posted in the COVID-19 Vaccine Webinar Series section: https://www.cdc.gov/vaccines/covid-19/training-education/webinars.html

NEW The COVID-19 Vaccine Quick Reference Guide for Healthcare Professionals is a quick reference for comparing general information, storage and handling information, and vaccine administration information for all COVID-19 vaccines.

NEW These Interim Clinical Considerations and new reference materials are ready for use:
- The Interim Clinical Consideration Summary provides an easy reference of clinical considerations.
- The Vaccine Administration Errors and Deviations table is an easy reference for information on handling vaccine administration errors.

NEW NIAID Statement on AstraZeneca Vaccine
NEW The Centers for Medicare & Medicaid Services (CMS) released an update to the Coverage and Reimbursement of COVID-19 Vaccines, Vaccine Administration, and Cost Sharing under Medicaid, CHIP, and BHP vaccine toolkit. This version of the toolkit reflects the updated Medicare vaccine administration payment rates. The American Rescue Plan Act (ARPA)(P.L. 117-2) was signed by President Biden on March 11, 2021 and included 100 percent FMAP for vaccines as well as an expansion of individuals eligible for vaccine administration coverage. The toolkit does not yet reflect all changes made by the ARPA and will be updated to reflect the legislation shortly. Learn more here: Vaccine Toolkit

NEW CMS: Biden Administration Increases Medicare Payment for Life-Saving COVID-19 Vaccine

NEW On March 15, 2021, the FDA launched the COVID-19 EUA FDA Adverse Events Reporting System (FAERS) Public Dashboard providing weekly updates of adverse event reports submitted to FAERS for drugs and therapeutic biological products used under an EUA during the COVID-19 public health emergency.

Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination — This guidance applies to all healthcare personnel (HCP) while at work and all patients and residents while they are being cared for in a healthcare setting. CDC has updated select healthcare infection prevention and control recommendations in response to COVID-19 vaccination, which are summarized in this guidance

Communication Tools

CDC: When You’ve Been Fully Vaccinated


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.

COVID-19 Vaccination — The COVID-19 vaccination website 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.

COVID-19 Vaccination Communication Toolkit — Medical centers, clinics, and clinicians can use or adapt these ready-made materials 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
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.

CDC: Understanding the Federal Retail Pharmacy Program for COVID-19 Vaccination

CDC: What Older Adults Need to Know about COVID-19 Vaccines

National Forum on COVID-19 Vaccine — The National Forum on COVID-19 Vaccine shared a variety of materials and resources to help support COVID-19 vaccination. Here you will find practical resources about how to provide vaccine equitably, effectively, and quickly to as many people as possible in communities across the country.

FDA posted the webpage, COVID-19 Vaccine Safety Surveillance, which provides an overview of our active and passive systems used to monitor the safety of authorized COVID-19 vaccines.

Information for those Administering the Vaccine including Clinical Guidelines

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

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.

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

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:

- New recommendations for preventing, reporting, and managing mRNA COVID-19 vaccine administration errors (Appendix A).
- Clarification on contraindications and precautions.
- Updated information on delayed, local injection-site reactions after the first mRNA vaccine dose. These reactions are neither a contraindication or precaution to the second dose.

Additionally, the quarantine recommendations for fully vaccinated persons who meet certain criteria were updated. There are public health considerations for vaccinated individuals, including patients and residents in healthcare settings, which are summarized here: Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines

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.

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.

The FDA issued guidances for medical product developers, specifically covering vaccines, diagnostics and therapeutics products, to address the emergence and potential future emergence of variants of SARS-CoV-2, the virus that causes COVID-19.

Anaphylaxis and other post-vaccination information


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.


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...
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. These considerations 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.

Employer information

EEOC Withdraws Proposed Wellness Incentive Rules — Increasing Employer COVID-19 Vaccination Incentive Uncertainties

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.

In response to President Biden’s executive order, the Occupational Safety and Health Administration (OSHA) has released revised guidance for employers. The new guidance includes recommendations that employers provide vaccines to eligible employees, implement COVID-19 prevention programs, and provide face coverings to all employees, whether they have been vaccinated or not.

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.

Coverage Information

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
Data and Analysis

**CDC COVID Data Tracker** — Vaccinations are now being tracked on [CDC's COVID Data Tracker](https://covid.cdc.gov/covid-data-tracker/index.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.

**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](https://v-safe.hhs.gov) 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.

**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](https://www.cdc.gov/coronavirus/2019-ncov/science-update/).

Additional resources

**CDC/NIOSH Resources**
- [Ensuring the Proper PPE when Administering COVID-19 Vaccine](https://www.cdc.gov/vaccinesafety/covid-19-ppe.html)
- [Preventing Needlesticks in Health Care Settings (Also Available in Spanish)](https://www.cdc.gov/vaccines/hcp/COVID-19/prevent-needlesticks.html)
- [Preventing Needlesticks and Sharps Injuries](https://www.cdc.gov/vaccines/hcp/COVID-19/prevent-needlesticks.html)
- [Stop Sticks Campaign](https://www.cdc.gov/vaccines/hcp/COVID-19/prevent-needlesticks.html)
- [What Every Worker Should Know: How to Protect Yourself From Needlestick Injuries (Also Available in Spanish)](https://www.cdc.gov/vaccines/hcp/COVID-19/prevent-needlesticks.html)

**OSHA Resources**
- [Bloodborne Pathogens and Needlestick Prevention](https://www.osha.gov/dts/osta/otm/otm热血传奇/otm热血传奇.html)
- [Healthcare Wide Hazards Needlestick/Sharps Injuries](https://www.osha.gov/dts/osta/otm/otm热血传奇/otm热血传奇.html)


Other CDC Resources
- [Recipient education](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/education.html), including making a strong recommendation, answering questions, and understanding and explaining mRNA vaccines
- [Planning and partnerships](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/education.html)
- [Vaccination toolkits](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/education.html)