## COVID Vaccine Information

**Key attributes of the COVID vaccines which have received Emergency Use Authorization (EUA) or full approval 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><strong># of doses (initial series), not immunocompromised</strong></td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td><strong># of doses (initial series), immune-compromised</strong></td>
<td>3</td>
<td>3</td>
<td>n/a</td>
</tr>
<tr>
<td><strong>Booster dose</strong></td>
<td>Booster dose does not need to be the same product.</td>
<td>Booster dose does not need to be the same product.</td>
<td>Booster dose does not need to be the same product.</td>
</tr>
<tr>
<td><strong>Interval between doses for initial series, not immunocompromised</strong></td>
<td>28 days</td>
<td>21 days</td>
<td>n/a</td>
</tr>
<tr>
<td><strong>Interval to third dose (immunocompromised)</strong></td>
<td>28 days</td>
<td>28 days</td>
<td>n/a</td>
</tr>
<tr>
<td><strong>Interval for boosters (after initial series)</strong></td>
<td>6 months</td>
<td>6 months</td>
<td>2 months</td>
</tr>
<tr>
<td><strong>NEW: Lower age bound</strong></td>
<td>18 years for both initial series and booster</td>
<td>5 years for initial series, 16 years for booster</td>
<td>18 years for both initial series and booster</td>
</tr>
<tr>
<td><strong>Product type</strong></td>
<td>mRNA/liquid nanoparticle</td>
<td>mRNA/liquid nanoparticle</td>
<td>DNA/adenovirus (viral vector)</td>
</tr>
<tr>
<td><strong>Dilution required</strong></td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td><strong>Submission of BLA</strong></td>
<td>June 1, 2021</td>
<td>May 7, 2021</td>
<td>Expected 2021</td>
</tr>
<tr>
<td><strong>Emergency Use Authorization</strong></td>
<td><strong>December 18, 2021</strong></td>
<td><strong>December 11, 2021</strong></td>
<td><strong>February 27, 2021</strong></td>
</tr>
<tr>
<td><strong>Full Authorization Status (BLA approved)</strong></td>
<td><strong>August 23, 2021</strong> (16 years +)</td>
<td><strong>Here</strong></td>
<td><strong>Here</strong></td>
</tr>
<tr>
<td><strong>FDA Fact sheets</strong></td>
<td>Here</td>
<td>Here</td>
<td>Here</td>
</tr>
<tr>
<td><strong>CDC Interim clinical considerations</strong></td>
<td>Here</td>
<td>Here</td>
<td>Here</td>
</tr>
<tr>
<td><strong>CDC FAQs</strong></td>
<td>Here</td>
<td>Here</td>
<td>Here</td>
</tr>
<tr>
<td><strong>ACIP recommendations</strong></td>
<td>Here</td>
<td>Here</td>
<td>Here</td>
</tr>
<tr>
<td><strong>Other CDC resources</strong></td>
<td>Here</td>
<td>Here</td>
<td>Here</td>
</tr>
</tbody>
</table>
NEW:  Press Release:  FDA Expands Eligibility for Pfizer-BioNTech COVID-19 Booster Dose to 16- and 17-Year-Olds

OSHA, CMS Release Vaccine Mandate Regulations – The Occupational Safety and Health Administration (OSHA) has released its emergency temporary standard (ETS) mandating COVID-19 vaccinations or weekly testing of workers at companies with 100 or more employees. The rule requires covered employers to develop, implement, and enforce a mandatory COVID-19 vaccination policy or require employees to undergo regular COVID-19 testing and wear a face covering at work. Each violation of the rule could result in a fine of up to $13,653, and willful violations could lead to a fine as high as $136,532. The first compliance deadline is set for December 6, when employers must have established, implemented, and begun enforcing a written vaccination policy; begin providing paid time off for workers to get vaccinated, as well as time off for recovery from side effects; and ensure that those covered employees who are not inoculated are wearing masks, among other requirements. Covered employees must be fully vaccinated or submit to testing starting January 4. States with their own OSHA-approved workplace safety and health plans can decide whether to accept the standard or choose to draft an equivalent or more protective rule. The ETS was announced in conjunction with an interim final rule with comment period (IFC) from the Centers for Medicare and Medicaid Services (CMS) to require health care workers at approximately 76,000 Medicare and Medicaid participating hospitals and other facilities to be vaccinated. This regulation does not offer an option for workers to get tested regularly instead of vaccination, but (like the ETS) it does provide for medical or religious exemptions. The regulation covers employees, students, people in training, volunteers, and those who provide services under contract, but (like the ETS) it does not apply to people who work only remotely. Facilities that do not comply with the rule could face civil monetary penalties, payment denials, or be terminated from the Medicare and Medicaid programs. The health-care worker vaccine mandate also follows a phased-approach, where all staff must be vaccinated by January 4. In addition, recognizing the potential need for clarification regarding reasonable accommodation, the EEOC update its guidance on October 28.

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

Learn More About COVID-19 Vaccines From the FDA

CDC has designed a 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

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.

These Interim Clinical Considerations and 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.

NIAID Statement on AstraZeneca Vaccine

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.

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

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.

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.

COVID-19 Vaccines for Moderately to Severely Immunocompromised People — On August 13, 2021, ACIP outlined clinical recommendations regarding an additional dose of COVID-19 vaccine for certain immunocompromised individuals. Because people with moderately to severely compromised immune systems may not build the same level of immunity to 2-dose vaccine series compared to people who are not immunocompromised, the CDC is recommending that these individuals receive an additional dose of mRNA COVID-19 vaccine at least 28 days after a second dose of Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine to make sure they have enough protection against COVID-19. This additional dose, intended to improve immunocompromised people’s response to their initial vaccine series, is not the same as a booster dose, given to people when the immune response to a primary vaccine series is likely to have waned over time.

Communication Tools

CDC: When You’ve Been Fully Vaccinated


NIOSH COVID-19 Vaccine Communication Toolkit for Essential Workers

A communication toolkit is available to help employers build confidence in their workforce for this important 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 patient reporting platform. Read more in this 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:

- 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
CDC published Clinical Considerations for myocarditis and pericarditis following COVID-19 vaccination. Additionally, resources for the public have been added to CDC’s website that can be a resource for your patients. CDC and its partners are actively monitoring these reports, by reviewing data and medical records, to learn more about what happened and to see if there is any relationship to COVID-19 vaccination.
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 and May 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 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.

On August 13, OSHA updated its guidance, with changes to include:
Reflecting the July 27, 2021 Centers for Disease Control and Prevention (CDC) mask and testing recommendations for fully vaccinated people,

Reorganizing the Appendix recommendations for Manufacturing, Meat and Poultry Processing, Seafood Processing, and Agricultural Processing Industries, and

Adding links to guidance with the most up-to-date content.

OSHA Issues Emergency Temporary Standard for Healthcare and Updated Guidance for All Industries — The Occupational Safety and Health Administration (OSHA) has issued an emergency temporary standard (ETS) to protect healthcare and healthcare support service workers from occupational exposure to COVID-19 in settings where people with COVID-19 are reasonably expected to be present. During the period of the emergency standard, covered healthcare employers must develop and implement a COVID-19 plan to identify and control COVID-19 hazards in the workplace. A factsheet summarizing the ETS is available here: Subpart U—COVID-19 Healthcare ETS (osha.gov). Any questions about these materials should be directed to your OSHA regional or local office: https://www.osha.gov/contactus/bystate.

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.

In May 2021, the HHS Office of Inspector General (OIG) posted an answer to the FAQ: "Would the offer or provision of cash, cash-equivalent, or in-kind incentives or rewards to Federal health care program beneficiaries who receive COVID-19 vaccinations during the public health emergency violate OIG’s administrative enforcement authorities?" Read OIG's Response.

Coverage Information
On December 17, 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, 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. 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 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.

Additional resources
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