

NOTE: This resource was originally published in 2020 and updated in 2021. It is not being maintained. While information contained within was current when published, it may be outdated, and some links may not work. Please refer to ASPR TRACIE's [COVID-19 Vaccination Quick Links](#) for current information.

ASPR TRACIE Technical Assistance Request

Request Receipt Date (by ASPR TRACIE): December 11, 2020

Response Date: December 16, 2020; **Updated May 19, 2021**

Type of TA Request: Complex

Request:

ASPR TRACIE received a request for information related to the approval, allocation, distribution, and administration of vaccines to prevent COVID-19 within healthcare facilities.

Response:

The ASPR TRACIE Team reviewed existing resources, including those in our [Mass Distribution and Dispensing of Medical Countermeasures](#), [Influenza Epidemic/Pandemic](#), [Ethics](#), and [Responder Safety and Health](#) Topic Collections and on our [COVID-19 Resources Page](#). We also conducted a search online for relevant materials. Information from these materials is gathered and provided as points for consideration in this document.

The information below is intended to provide high level considerations for vaccination administration and planning in healthcare facilities. Additional information may be found in the [COVID-19 Vaccine Resources Collection](#). (Updated December 31, 2020)

Please refer to the Centers for Disease Control and Prevention's [Coronavirus Disease 2019 webpage](#) and the [NIH COVID-19 Treatment Guidelines](#) for the most up-to-date clinical guidance on COVID-19 outbreak management.

I. COVID-19 Vaccine Considerations

Vaccine Development and Approval: Development of a vaccine to prevent COVID-19 has proceeded at an unprecedented pace. Building on years of research on coronaviruses and with the support of purchase commitments from national governments, manufacturers focused on COVID-19 vaccine development and produced several vaccines authorized for use less than a year after the SARS-CoV-2 virus was first recognized.

- More than 200 vaccines began development around the world using various technologies. Some of these technologies have been used in the past to prevent other illnesses, such as live attenuated vaccines for measles, inactivated vaccines for influenza, and protein sub-

unit vaccines for pertussis. Some of the most promising COVID-19 vaccines use two newer technologies: viral vector-based vaccines (previously used for Ebola virus disease) and nucleic acid vaccines. The viral vector-based vaccines use well-established technology and elicit a strong immune response, but they are complex to manufacture and there are concerns that previous exposure to the vector may affect effectiveness. Nucleic acid vaccines – including messenger RNA (mRNA) – are easier to manufacture and have no risk of triggering disease but had previously only been approved for use in animals and some require ultra-cold storage.

- Each country has its own process for reviewing the safety and effectiveness of vaccine candidates and authorizing their use by the public.
- COVID-19 vaccines are not administered in the U.S. until they are authorized by the Food and Drug Administration (FDA). The Emergency Use Authorization (EUA) process used so far does not constitute full approval or licensing for the vaccine but allows administration while an emergency declaration is in place when the current evidence favors the known benefit versus risk.
- (Updated March 1, 2021) Three vaccines – from [Pfizer/BioNTech](#), [Moderna](#), and [Johnson & Johnson/Janssen](#) – are authorized in the U.S. as of March 1, 2021. Additional vaccines authorized for emergency use in other nations since the summer of 2020 include:
 - [AstraZeneca/Oxford University](#) (Covishield/Vaxzevria)
 - [Bharat Biotech](#) (Covaxin)
 - [CanSino Biologics/Beijing Institute of Biotechnology Ad5-nCoV](#) (Convidecia)
 - [Chumakov Centre \(CoviVac\)](#)
 - [Gamaleya Research Institute of Epidemiology and Microbiology](#) (Sputnik V)
 - [Sinopharm BBIBP-CorV](#)
 - [Sinovac](#) (CoronaVac)
 - [Vector](#) (EpiVacCorona)
- Following its [EUA](#) in the U.S. by the FDA on December 11, the Advisory Committee on Immunization Practices (ACIP) issued an [interim recommendation](#) for the use of the Pfizer/BioNTech vaccine in those age 16 and older on December 13, 2020. **The FDA expanded the EUA to allow use in those 12 to 15 years of age on May 10, 2021 and ACIP recommended use in that age group on May 12. (Updated May 19, 2021)**
- Similarly, the FDA issued an [EUA](#) for the Moderna vaccine on December 18 followed by an [interim recommendation](#) from ACIP on December 19 for its use in those age 18 and older. (Updated December 21, 2020)
- The FDA issued an [EUA](#) for the Johnson & Johnson/Janssen vaccine on February 27 followed by an [interim recommendation](#) from ACIP on February 28 for its use in those age 18 and older. (Updated March 1, 2021)
- [Section II](#) includes information on the status of vaccines authorized for use in the U.S. and vaccine candidates with promising results in late stage trials for which manufacturers may seek approval in the U.S. in the coming months.

- Variants to the SARS-CoV-2 virus continue to be identified throughout the world. So far, the vaccines authorized for use in the U.S. appear to be effective against the most prevalent variants, but concern exists about vaccine effectiveness against future mutations. Moderna announced [two studies](#) to prepare for this threat: testing a booster dose of its existing vaccine and developing an emerging strain booster candidate. Pfizer/BioNTech [announced](#) a study of safety and immunogenicity of a third dose of its existing vaccine and is exploring modifications to its vaccine. The FDA [indicated](#) a streamlined process will be used to test and authorize alterations to already authorized vaccines that make them more effective against virus variants. (Updated March 1, 2021)

Vaccine Options: While experience developing other vaccines suggests that many of the current COVID-19 candidates will not be approved for use, several vaccines to prevent COVID-19 are already available, mostly for emergency use ([refer to chart in Section II](#)).

- The availability of multiple vaccines in 2021 has complicated decision-making for those ordering vaccines. Amounts of each vaccine available, booster dosing, the setting in which vaccines are administered, effectiveness against virus variants, and the populations needing to be vaccinated are factors to consider. (Updated March 1, 2021)
- Some vaccines may be more efficacious in certain populations than others. As more data becomes available and eligibility is extended to the general population, those ordering vaccine should maintain awareness of any emerging differences in effectiveness in specific populations, such as older adults or children, and place orders appropriate to the population they serve.
- With several vaccines available, it may be possible to select a product with characteristics more suitable for the setting in which it will be administered. For instance, early in the vaccine rollout, supplies of vaccine requiring ultra-cold storage were directed to academic medical centers and large hospitals with the logistical capacity to manage them while vaccines that can be stored at refrigerator temperatures may be more suitable for physician offices or pharmacies.

Supply and Allocation: The initial supply of vaccine was limited and continues to grow as additional vaccines are approved and production increases.

- To encourage vaccine development, governments around the world made purchasing commitments that encouraged manufacturers to begin producing vaccines prior to the completion of their clinical trials, thereby ensuring the availability of an initial, limited supply upon FDA authorization of each vaccine. Supplies will increase as production continues to ramp up and additional vaccines are authorized.
- Due to the initial limited supplies, a phased approach was necessary to prioritize which segments of the population were vaccinated first. Various governments and organizations offered frameworks for the fair and ethical allocation of limited vaccine supplies, including the [National Academies of Sciences, Engineering, and Medicine](#), [ACIP](#), and the [World Health Organization](#). Most of these frameworks included considerations for healthcare and other essential workers, older adults, and communities of color that have been disproportionately affected by the COVID-19 pandemic.

- In the U.S., ACIP identified approximately 24 million [healthcare workers and residents of long-term care facilities](#) as the highest priority groups for the initial allocation of COVID-19 vaccine during Phase 1a. ACIP met on December 20 to [recommend](#) essential frontline workers and those age 75 and older as the next prioritized groups in Phase 1b and other essential workers, those age 65 and older, and those with high-risk medical conditions in Phase 1c. (Updated December 21, 2020) The Secretary of Health and Human Services [announced](#) on January 12 that vaccination eligibility would be expanded to the Phase 1c priority group. **On March 11, the President [announced](#) that all adults in the U.S. would be eligible to be vaccinated by May 1.** (Updated May 19, 2021) Healthcare providers should maintain awareness of the eligibility criteria in the jurisdiction in which they practice. (Updated March 1, 2021)
- In the U.S., five federal agencies – the Bureau of Prisons, Department of Defense, Department of State, Indian Health Services, and Veterans Health Administration – were allocated their own supply of vaccine to prioritize among their staff and populations they serve. Additionally, federal agreements allowed long-term care facilities to opt-in to having vaccine administered to their residents by CVS and Walgreens; **this Long-Term Care Pharmacy Partnership ended in April.** (Updated May 19, 2021) On February 8, the federal government began rollout of the [Federal Retail Pharmacy Program](#) to expand the number of COVID-19 vaccination access points. During the week of February 15, the federal government began allocating vaccine to federally-funded health centers serving a large volume of disproportionately affected populations; the [Health Center COVID-19 Vaccine Program](#) **expanded to all 1,470 health centers on April 7.** (Updated May 19, 2021) These allocations are in addition to what is allocated to states and territories; jurisdictions should consider these federal distribution efforts in their own prioritization decisions.

Transportation and Storage: Vaccines vary in their transportation and storage requirements, ranging from those that may be stored at normal refrigerator temperatures to those requiring ultra-cold storage. It is critical those ordering vaccine understand the transportation and storage requirements associated with the ordered product and can support those requirements.

- Vaccine coordinators must be pre-identified at each shipping site to receive vaccine shipments and monitor its storage and supply.
- Due to its ultra-cold chain storage requirements, Pfizer developed [shipping containers](#) for its vaccine. Vaccine recipients should understand these shipping containers, including their size and weight, how long shipped vaccine can remain in the shipping container, how frequently the container may be opened, how to store vaccine once it is removed from the container, and plan for pelletized dry ice replenishment if required. On February 25, the FDA [updated](#) its fact sheet for healthcare providers to reflect its decision to allow transportation and storage of undiluted frozen vials of the Pfizer/BioNTech at conventional temperatures for up to two weeks. (Updated March 1, 2021) **The fact sheet was later [updated](#) to indicate that undiluted, thawed vials could be stored at refrigerator temperatures for up to one month.** (Updated May 19, 2021) Each

shipment of this vaccine includes 975 doses in multi-dose vials (1,170 doses can be obtained when using low dead-volume needles/syringes). (Updated March 1, 2021)

- Orders for Moderna and Johnson & Johnson/Janssen are a minimum of 100 doses per order.
- Health systems should consider central ordering for their affiliated hospitals, clinics, and other providers. Healthcare coalitions may have a role in coordinating orders and central shipping locations for participants, particularly in rural areas where facilities have limited staff and population served.
- Dry ice is a high demand product due to its use in vaccine shipments on top of its normal uses. Vaccine recipients should identify back-up sources of dry ice and train staff on the safe handling of dry ice. Have dry ice gloves in various sizes readily available.
- Emergency plans should account for the uninterrupted power supply needs of vaccine storage areas and identify generators or other back-up options to protect the vaccine supply in the event of a power outage.
- Many states require their boards of pharmacy to inspect freezers or mandate continuous monitoring of temperatures.

Logistics: In addition to the transportation and storage issues, vaccine distribution and administration involve numerous challenges.

- Vaccine providers must be pre-enrolled to be eligible for vaccine ordering and receipt. This requires outreach to recruit vaccine providers, completion of the enrollment process, and training on vaccine provider requirements, such as vaccine administration techniques and necessary reporting.
- Sites must be prepared to receive the vaccine itself and the [ancillary supplies](#) included in each kit. These kits do NOT include sharps containers, gloves, or bandages. Vaccine providers should understand what ancillary supplies will be provided and what additional supplies may be needed to support vaccine administration efforts.
- Security will be needed for both the vaccine storage site and the location where vaccine is administered.
- As supply increases and eligibility is extended to additional groups, healthcare facilities should engage in planning with healthcare coalitions and other community partners about their role in vaccination efforts. (Added March 1, 2021)
- Healthcare facilities should consider their full range of staffing needs. This includes not only vaccine providers, but also staff for planning, vaccine and related supply ordering, transport and storage, security, communications, finance, information technology, and administrative reporting. All staff should be trained on their expected roles.
- Use of multi-dose vials requires planning to avoid wastage. While Pfizer/BioNTech vaccine labels indicate there are five doses per vial, those preparing vaccine for administration should be [aware that a sixth dose can be obtained](#) when using low dead-volume syringes and needles. (Updated March 1, 2021) **Moderna vaccine comes in [two multi-dose vial presentations](#): one with 10-11 doses and the other with 13-15 doses, depending on the needles and syringes used to extract doses.** (Updated May 19, 2021)

- Vaccines administered under EUA will require the recipient review and provide consent. Ideally, these forms should be made available for review prior to the time of vaccination to speed the process.
- Some of the vaccines will require two doses at a different number of days between doses depending on the vaccine. Tracking is needed to ensure that individuals receive both doses of the same vaccine at the correct interval.
- Extensive reporting requirements are in place to track both the vaccine and the vaccinated. Healthcare facilities and providers should understand reporting requirements and ensure systems are in place to support them.

Adverse Events: As with all vaccines, some localized and systemic side effects are expected with vaccines to prevent COVID-19. **In rare instances, serious adverse events have occurred following vaccination. (Updated May 19, 2021)**

- Healthcare facilities should ensure staff know how to report adverse events to the Vaccine Adverse Event Reporting System ([VAERS](#)), have strategies in place to minimize their impact on operations (e.g., do not vaccinate an entire unit staff at the same time), and have paid time off and return to work policies in place for staff who experience symptoms post-vaccination.
- **Clinicians should be familiar with [healthcare provider instructions](#) for screening of patients' eligibility for vaccine based on ACIP contraindications and precautions recommendations. Healthcare facilities should have a process in place to monitor safety alerts and updated recommendations and to share that information with staff. (Updated May 19, 2021)**
- Vaccine administration sites should have [medications and supplies](#) in place for the assessment and initial management of anaphylaxis, a potential rare adverse event following COVID-19 vaccination. (Updated December 21, 2020)
- **A [small number of cases](#) of thrombosis with thrombocytopenia syndrome (TTS) have been reported in those who received the Johnson & Johnson/Janssen vaccine. Following a brief pause in administration of the vaccine to raise awareness among clinicians of these potential adverse effects and to further examine the risks and benefits of the vaccine, the CDC and FDA recommended administration of the vaccine be resumed on April 23 with an updated [EUA](#) and accompanying healthcare provider and recipient and caregiver fact sheets with warnings about the potential for TTS. (Updated May 19, 2021)**

Vaccination Confidence: The success of the COVID-19 vaccination effort is dependent on accurate and effective communications among response partners and risk communication to the public.

- Due to historic and systemic healthcare inequities, some members of populations most at risk of severe illness and death from COVID-19 are hesitant to receive the newly-authorized vaccines that could significantly reduce those risks. Healthcare facilities and providers should [educate](#) all patients about the importance of vaccination and eligibility to be vaccinated. (Updated March 1, 2021)

- Other individuals are concerned about potential near and long-term side effects of the vaccine, the safety of vaccines developed so quickly, the lack of evidence on the effects of the vaccine in some populations (e.g., pregnant people, children, older adults, immunocompromised persons) due to their exclusion or limited representation in clinical trials, or distrust in new technologies used to develop the vaccines. They may be hesitant to be vaccinated until they believe more information is available about the safety and effectiveness of the new vaccines. (Updated March 1, 2021)
- Vaccine hesitancy also extends to the healthcare workforce. Among participants in the Pharmacy Partnership for Long-Term Care Program, only a median of [37.5% of staff received at least one dose of vaccine](#) during the first month of the program compared to a median of 77.8% of long-term care facility residents. (Updated March 1, 2021)
- **Healthcare facilities should determine whether COVID-19 vaccination is mandatory for all staff. If so, the employee vaccination plan should be accompanied by a policy that includes waivers and exemptions. The policy should also include considerations for staff who are categorized as being in high-risk groups for which vaccination is not recommended. Many healthcare facilities already have these types of policies for [seasonal influenza vaccination](#), which can be modified for COVID-19.** (Updated May 19, 2021)
- Misinformation and disinformation about COVID-19 vaccines began circulating before vaccines even became available, adding to vaccine hesitancy. Anti-vaccination activists and others skeptical of the safety and effectiveness of authorized vaccines have disrupted vaccination clinics and sabotaged supplies in the U.S. Regulatory documents obtained via a cyberattack in the European Union were altered to bring the safety of vaccines under review into question. (Updated March 1, 2021)
- Healthcare facilities and providers should be aware of and share sources of accurate, evidence-based [information](#) to address staff and patient concerns, boost vaccine confidence, and counter misinformation. Willingness to be vaccinated has grown as the number of persons safely vaccinated has increased; providers should be prepared to engage in ongoing conversations with patients who initially decline offered vaccine. (Updated March 1, 2021) **Resources are available to help healthcare providers communicate with patients about vaccination.** (Updated May 19, 2021)
- Consistent and coordinated risk communications can reduce confusion and build vaccine acceptance among the public as vaccine becomes available to additional segments of the population.
- Healthcare coalitions may have a role in supporting information sharing among hospitals, clinics, physician offices, long-term care facilities, pharmacies, and other vaccine administration sites to ensure coordinated and equitable vaccine coverage in the community as supply increases.

(Updated March 1, 2021) **Demand:** In the early months of vaccine distribution in the U.S., demand outpaced supply. Various strategies were considered to increase supply.

- The U.S. government entered into [additional purchasing agreements](#) that are expected to deliver 600 million doses of vaccine by the end of July 2021.
- The FDA [amended](#) the Pfizer/BioNTech vaccine EUA to clarify that six doses rather than five could be drawn from each vial when using low dead-volume syringes and needles, potentially adding millions of doses to the available supply. This type of syringe is now being [included](#) in the ancillary kits distributed with vaccines.
- Sanofi [agreed](#) to manufacture 125 million doses of Pfizer/BioNTech vaccine beginning in the summer of 2021, which will help to boost manufacturing capacity. Novartis has also [pledged](#) to support production of the Pfizer/BioNTech vaccine. Additionally, the [Defense Production Act](#) was invoked to help Merck update two facilities to manufacture the Johnson & Johnson/Janssen vaccine and to provide logistical support to Johnson & Johnson.
- Much discussion has centered on delaying the second dose of vaccines with a two-dose regimen to increase the number of people who can receive the first dose, as was first implemented in the [United Kingdom](#). CDC guidance allows for up to [42 days](#) between doses.
- Criminals have taken advantage of the demand by offering non-existent vaccine doses or priority access to vaccination in exchange for payment and tricking those seeking vaccine into sharing personal information such as Social Security numbers. Healthcare facilities and providers should maintain awareness of [fraud alerts](#) issued by government agencies and be prepared to direct patients to [reputable information sources](#) and provide [advice](#) about avoiding vaccine-related scams.

Funding: Because the U.S. government is purchasing vaccines from the manufacturers, members of the public will not be charged for vaccines. However, there are costs associated with the mass vaccination effort.

- While individuals cannot be charged for the cost of the vaccine itself, they may be charged a vaccine administration fee. This administrative cost may be billed to the individual's [health insurer](#), [Medicare](#), [Medicaid](#), the [Children's Health Insurance Program](#), or the [COVID-19 Uninsured Program](#). [The COVID-19 Coverage Assistance Fund enables reimbursement to providers at the national Medicare rate for vaccine administration costs of patients whose health insurance does not cover vaccine administration fees. \(Updated May 19, 2021\)](#)
- The Centers for Disease Control and Prevention (CDC) [awarded](#) \$200 million to the 64 jurisdictions required to submit COVID-19 vaccination plans yet the CDC Director [estimated](#) that \$5.5-6 billion would be needed to distribute vaccine. The Adult Vaccine Access Coalition [requested](#) \$8.4 billion to modernize immunization information systems, recruit and train the immunization workforce, promote mass vaccination, remove financial access barriers, and compensate providers for various costs. The federal government [announced](#) in January that an additional \$3 billion would be made available to the 64 jurisdictions to support their vaccination efforts. (Updated March 1, 2021)

- The Federal Emergency Management Agency (FEMA) is partnering with state and local jurisdictions on [federal pilot community vaccination centers](#) and is reimbursing state, local, tribal, and territorial governments at 100 percent for use of the [National Guard](#) in vaccination efforts until September 20, 2021. (Updated March 1, 2021)
- In addition to billing payers for vaccine administration costs, healthcare facilities and providers should accurately document all expenses related to COVID-19 vaccination planning and response efforts. Reimbursement and cost recovery may be available through the various federal and state programs established with COVID-19 relief funding.

II. FDA Authorized Vaccines and Most Promising Candidates

The vaccine development and approval processes are fluid and information updates frequently. This table is not a comprehensive summary of vaccine approvals worldwide; it focuses on vaccines authorized for use in the U.S. or in late stage trials and expected to be submitted for approval by FDA in the coming months. The information in this table is current as of May 19, 2021.

Vaccine Sponsor	Technology	Dosing	Efficacy	Storage	Supply Forecast	Status
Pfizer/ BioNTech ^{1,2} (COMIRNATY®)	mRNA	2 doses 21 days apart	<ul style="list-style-type: none"> 95% efficacy common adverse reactions: injection site reactions, fatigue, headache, muscle pain, chills, joint pain, fever; and the second dose is associated with a higher incidence of side effects than the first UK recommended against use in those with a history of anaphylaxis to a vaccine, food, or medicine In vitro studies demonstrated neutralizing activity against emerging strains 	<ul style="list-style-type: none"> Transportation & long-term storage at -70° Celsius³ Developed shipping containers Conducted pilot delivery program in 4 states 	US purchased 100 million doses that have begun to be distributed; a second purchase of 100 million doses will be delivered by July 31, with an option to purchase an additional 400 million doses; that option was exercised for a third purchase of 100 million doses; other agreements commit 300 million doses to the EU & 40 million doses to COVAX in 2021	<ul style="list-style-type: none"> Submitted request for emergency use authorization (EUA) to the Food and Drug Administration (FDA) on November 20. FDA's Vaccines and Related Biological Products Advisory Committee met to discuss the request on December 10. FDA issued an EUA on December 11, which was amended May 10, 2021 to expand use to 12-15 year-olds. ACIP issued an interim recommendation for use of the vaccine on December 13 for those 16 and older & those ages 12-15 on May 12, 2021. Authorized for use in the United Kingdom on December 2, Bahrain on December 6, Canada on December 9, Saudi Arabia on December 10, Mexico on December 11, Kuwait on December 13, Singapore and Jordan on December 14, Costa Rica and Ecuador on December 15, Chile, Oman and Panama on December 16, Switzerland on December 19, and the European Union on December 21. As of May 19, the vaccine was authorized or approved by 98 regulatory bodies. The United Kingdom began administering the vaccine to prioritized

¹ [Pfizer-BioNTech COVID-19 Vaccine \(BNT162, PF-07302048\) Vaccines and Related Biological Products Advisory Committee Briefing Document](#)

² [Pfizer-BioNTech COVID-19 Vaccine](#)

³ On February 25, the FDA authorized transport and storage of undiluted frozen vials at conventional temperatures for up to 2 weeks as an [alternative](#) to the preferred storage at -80 to -60° Celsius.

Vaccine Sponsor	Technology	Dosing	Efficacy	Storage	Supply Forecast	Status
Moderna ^{4,5}	mRNA	2 doses 28 days apart	<ul style="list-style-type: none"> 94.1% efficacy Common adverse reactions: injection site pain, fatigue, myalgia, arthralgia, headache, erythema/redness at injection site Studies indicate vaccine retains neutralizing activity against tested variants of interest, including B.1.1.7 and B.1.351 	<ul style="list-style-type: none"> Long-term storage at -20° Celsius 	US purchased 200 million doses with option to purchase up to 300 million additional doses; this option was exercised to purchase an additional 100 million doses; delivery of 100 million doses expected in U.S. by the end of the first quarter of 2021, global production of 500-600 million doses expected in 2021	<p>healthcare workers and older adults on December 8.</p> <ul style="list-style-type: none"> Submitted request for EUA to the FDA on November 30. FDA's Vaccines and Related Biological Products Advisory Committee met to discuss the request on December 17. FDA issued EUA on December 18. ACIP issued an interim recommendation for use of the vaccine on December 19 for those 18 and older. Authorized in Canada on December 23. As of May 19, the vaccine was authorized or approved by 54 regulatory bodies.
Johnson & Johnson/ Janssen ^{6,7}	Non-replicating viral vector	Trials include 1 and 2 dose regimens	<p>1 dose regimen:</p> <ul style="list-style-type: none"> 66.9% efficacy 14 days after vaccination & 66.1% efficacy 28 days after vaccination in preventing moderate to severe COVID-19 76.7% efficacy 14 days after vaccination and 85.4% efficacy 28 	<ul style="list-style-type: none"> Transportation and storage at 2-8° Celsius 	US agreed to purchase 100 million doses if authorized, option for additional 200 million doses	<ul style="list-style-type: none"> Submitted request for EUA for 1 dose regimen to the FDA on February 4. FDA's Vaccines and Related Biological Products Advisory Committee met to discuss the request on February 26. FDA issued EUA on February 27. ACIP issued an interim recommendation for the use of the 1 dose vaccine regimen on February 28 for those 18 and older. As of May 19, the 1 dose vaccine regimen was authorized or approved by 47 regulatory bodies.

⁴ [FDA Briefing Document Moderna COVID-19 Vaccine](#)

⁵ [Moderna COVID-19 Vaccine](#)

⁶ [FDA Briefing Document: Janssen Ad26.COVS.S Vaccine for the Prevention of COVID-19](#)

⁷ [Janssen COVID-19 Vaccine](#)

Vaccine Sponsor	Technology	Dosing	Efficacy	Storage	Supply Forecast	Status
Johnson & Johnson/ Janssen (continued)			<p>days after vaccination in preventing severe/critical COVID-19</p> <ul style="list-style-type: none"> • Common adverse reactions: injection site pain, headache, fatigue, myalgia • Rare cases of thrombosis with thrombocytopenia syndrome have been reported • Available data from study participants in South Africa & Brazil show efficacy against emerging variants⁸ 			<ul style="list-style-type: none"> • Phase 3 trials ongoing for 2 dose regimen.
AstraZeneca/ Oxford University ⁹ (COVISHIELD/ VAXZEVRIA)	Non-replicating viral vector	2 doses with an interval between 4 & 12 weeks	76% efficacy after first dose, 82% efficacy after second dose	<ul style="list-style-type: none"> • Transportation and storage at 2-8° Celsius for up to 6 months 	US supported development of at least 300 million doses	<ul style="list-style-type: none"> • Authorized for use in the United Kingdom on December 30. As of May 19, the vaccine was authorized or approved by 144 regulatory bodies.
Novavax ¹⁰	Protein sub-unit	2 doses	89.3%	<ul style="list-style-type: none"> • Transportation and storage at 2-8° Celsius 	US agreed to purchase 100 million doses if authorized	<ul style="list-style-type: none"> • Phase 3 trials ongoing • Request for authorization pending by 8 regulatory bodies

⁸ [Janssen Biotech, Inc. \(A Pharmaceutical Company of Johnson & Johnson\) COVID-19 Vaccine Ad26.COV2.S VAC31518 \(JNJ-78436735\) Sponsor Briefing Document Addendum Vaccines and Related Biological Products Advisory Committee](#)

⁹ [COVID-19 Vaccine AstraZeneca Confirms 100% Protection Against Severe Disease, Hospitalisation, and Death in the Primary Analysis of Phase III Trials](#)

¹⁰ [Novavax COVID-19 Vaccine Demonstrates 89.3% Efficacy in UK Phase 3 Trial](#)