



FAQ: The COVID-19 Vaccines

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Which vaccines are currently available?

Currently there are two vaccines with emergency use authorizations (EUA) from the Food and Drug Administration (FDA). The first, from Pfizer, was endorsed by the FDA advisory panel on December 10 and received an EUA from the FDA on December 11. It showed 94% efficacy in trials. The first immunizations took place in the US the week of December 14.

The second, from Moderna, showed 94.5% efficacy in trials. Moderna received the FDA advisory panel endorsement on December 15 and the EUA on December 18. The first shots of the Moderna vaccine were administered the week of December 21.

Both vaccines require two doses three to four weeks apart.

How are the vaccines being distributed?

Vaccine distribution depends on the state/municipality. The Centers for Disease Control and Prevention (CDC) has outlined objectives for distribution (vaccine safety and effectiveness, decreasing instances of death and serious disease, reducing the burden the disease is having on society – economic, educational, etc. – and maximizing equity). From these objectives (and the CDC priority groups guidelines noted below), states/municipalities have developed their own distribution plans.

Since the December authorizations, most vaccinations are taking place at hospitals or public health clinics (so they would likely be primarily covered by medical benefits). But with the urgency of the initiative, the vaccine will also likely be available to the public at pharmacies like CVS, Walgreens, and others, as well as in-store pharmacies.

The Department of Health and Human Services' (HHS) strategy for distributing COVID-19 vaccines includes:



- Engaging with state, local and tribal health departments, territories, Tribes, and federal entities to allocate and distribute vaccines
- Direct distribution of the vaccine to commercial partners (CVS and Walgreens)
- Safe vaccine administration through additional partnerships to support proper storage and handling
- An IT vaccine tracking system for overall vaccine management

Federal officials initially expected a sufficient supply to immunize about 100 million people in the US by the end of February. Meeting this target relies heavily on execution. Additional supplies of the vaccine – from Pfizer and Moderna, and potentially other players who have vaccines at various stages of development – should be available in the spring and summer for those who are not in the priority groups.

Who gets the vaccine first?

The CDC's Advisory Committee on Immunization Practices (ACIP), a federal advisory committee comprised of medical and public health experts who develop recommendations on the use of vaccines in the US civilian population, recommended four groups for COVID-19 vaccination in the early phases:

- Healthcare personnel
- Workers in essential and critical industries
- People at high risk for severe COVID-19 disease due to underlying medical conditions
- People 65 years and older

From this recommendation, the CDC identified the following vaccine priority groups for states/municipalities:

- Phase 1a: health care personnel, long-term care facility residents
- Phase 1b: frontline essential workers, people 75 and older
- Phase 1c: people ages 65 74, people ages 16 64 with high-risk conditions, other essential workers
- Phase 2: people 16 and older not in phase 1

States are free to follow, or not follow, the CDC's recommendations on vaccine prioritization, and the current phase varies by state. Some states have entered phase 1b, while others remain in phase 1a.

For more detail on the CDC's priority groups, please see <u>Evidence Table for COVID-19 Vaccines Allocation in Phases 1b and 1c of the Vaccination Program.</u>

Is there support available for essential workers who want to be vaccinated?

If there is interest in vaccination support for essential workers as defined by the ACIP/CDC (or, if different, your state's jurisdiction), pharmacies (including CVS via this form) are helping organizations with their essential worker vaccination strategies. If all eligibility requirements are met for an on-site vaccination clinic, that option may be particularly useful if workers are concentrated in an area that does not provide convenient access to pharmacies or other providers providing vaccinations.

What are the requirements for setting up an on-site or dedicated vaccination clinic?

For clients or groups that meet a set of specific requirements, an on-site or dedicated COVID-19 vaccine clinic for essential workers may be an appropriate option. Eligibility requirements are as follows:

1,000 eligible essential workers that can be vaccinated at a single location



- The state/jurisdiction designates vaccine allocation to the organization specifically for their essential workers
- The chosen pharmacy has sufficient immunization staff in the geography or location of the group

How do I figure out the distribution plan for my state?

Even with the CDC guidance, each state determines who gets the vaccines when. It is important that employers refer to information from their state's public health department for specific distribution details, timelines and updates.

WebMD has compiled information and links to state-specific information; you can access it on the WebMD site.

How are pharmacies supporting the distribution of the vaccine?

Pharmacies like CVS, Walgreen's and others, as well as in-store pharmacies, are required to administer COVID-19 vaccines:

- In full compliance with all federal, state and local requirements
- In full compliance with other guidance, including patient prioritization requirements and recommendations

Individual states or jurisdictions will determine the activation and scope of phases 1b and 1c in the coming weeks. Pharmacies are prepared to support vaccination efforts once authorized to do so.

How do the vaccines work?

Both the Pfizer and Moderna vaccines use messenger RNA (mRNA). Instead of injecting a weakened germ, mRNA vaccines teach cells how to make a protein that triggers an immune response. This response produces antibodies that protect against infection. The Pfizer and Moderna offerings are the first authorized vaccines to use mRNA.

The success of the COVID-19 vaccines will pave the way for other mRNA vaccines, which can be produced faster and at a lower cost relative to traditional vaccines.

Are the vaccines safe?

Despite the review and authorization of two highly effective vaccines, there are lingering public concerns regarding the safety of the vaccines. The FDA has taken several steps to assure the public of its commitment to scientific rigor, integrity and transparency in their review of vaccine candidates.

- In June, the FDA issued clear guidance to drug manufacturers regarding its expectations for a clinical trial structure and related scientific data, which is required for the FDA evaluation processes.
- A Data and Safety Monitoring Board, comprised of fully independent research experts, reviewed
 emerging data from trials as they progressed and had the authority to pause or halt trials in the event of
 serious adverse events.
- Before the FDA began its review of the vaccines, the agency convened its Vaccines and Related Biological Products Advisory Committee to review aggregated trial data.

In an effort to promote and demonstrate vaccine safety, leading experts continue to issue public statements to



help allay concerns and encourage vaccinations.

What actions can employers take now to be ready when the vaccine is available more broadly?

For employers, this is the time to plan. Actions to consider include:

- Establishing a structure for developing a vaccination strategy (a committee or a task force)
- Surveying employees with broad questions (that will not elicit responses related to individual medical conditions) to get a sense of their perspectives (safety concerns, likelihood of getting vaccinated)
- Considering how to help procure or obtain vaccinations for your employees (assume full participation)
- Connecting with your insurance carrier to get a clear understanding of their plans, resources and ideas related to the vaccines
- Staying current with communications from your local health department
- Reaching out to wellness providers and vaccination providers to understand their approach and how it aligns with your organization's strategy

Communication is also critical. Keep your employees up to date with activities, plans and expectations. Amplify messages regarding vaccine safety now so concerns aren't an issue when the vaccine becomes available. Express your support of the vaccines as an important step in overcoming COVID-19, while reiterating the need to focus on safety to reduce infections and hospitalizations.

Finally, if your employees are working remotely, continue to support them with work-from-home and well-being resources. If they're in the office, remain diligent in executing workplace protocols (distancing, masks, cleaning). Encourage all employees – regardless of where they are working – to get a flu shot.

What are the expected administration costs for the vaccine?

As the vaccine is distributed to priority groups, information is emerging regarding employer administration costs. The following is a summary of details for employers to consider as they plan for 2021.

- Members will have \$0 cost-share (copayment, coinsurance or deductible), including when two doses are required (as is the case for the Pfizer and Moderna vaccines).
- The federal government will cover the cost for the vaccine itself as part of the Coronavirus Aid, Relief, and Economic Security (CARES) Act purchasing initial supplies of the vaccine and allocating them to the states for prioritized distribution.
- The CARES Act classifies COVID-19 vaccines as "preventive services," and they will be managed like
 other preventative vaccines, with administration through physicians' offices and pharmacies.
- Health plans and self-insured plans will be required to pay for the administration of the COVID-19 vaccine.
 - Administration cost for two dose vaccine: first dose \$16.94/second dose \$28.39
 - Administration cost for a single dose vaccine: \$28.39 [Should we note that there is not currently a single-dose vaccine in the market]
- Clients can cover vaccine administration costs through their medical benefit and/or their PBM pharmacy benefit. Given the HHS announcement regarding the federal government partnership with pharmacy



chains and community pharmacies to access and administer the vaccines, we encourage PBM clients to cover the administration fee under their PBM pharmacy benefit.

• Administration fees for Medicare plans will be covered by Medicare Fee For Service.

Can employers require employees to get the vaccine?

On December 16, the US Equal Employment Opportunities Commission (EEOC), which enforces workplace antidiscrimination laws, issued guidance on whether employers can mandate that employees be vaccinated. The guidance indicates that vaccines can be required, provided that accommodations are made for employees with qualifying disabilities or sincerely held religious beliefs that contradict receiving the vaccine.

Of course, in addition to a host of legal considerations, some of which are addressed in the EEOC guidance, there are a number of practical considerations associated with mandating that employees get vaccinated. Employers should evaluate their own workforce, operations and industry as part of determining how to address vaccinations for its employees.

Furthermore, while the guidelines around mandatory vaccinations are largely federal at this point, several states are considering their own guidance and/or legislation around the ability to make the vaccine mandatory. In the end, much will depend on the voluntary response and progress toward herd immunity. In other words, if the number of volunteers falls short and infection rates remain above certain levels, states may take legislative action to implement requirements.

Related Resources:

The Centers for Disease Control and Prevention

The US Department of Health and Human Services

WebMD: State-by-State Guide to COVID Vaccine Information (January 11, 2021)

Evidence Table for COVID-19 Vaccines Allocation in Phases 1b and 1c of the Vaccination Program

The US Equal Employment Opportunity Commission: "What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws" (December 16, 2020)

Stat: "FDA advisory panel endorses Pfizer/BioNTech Covid-19 vaccine" (December 10, 2020)

The Wall Street Journal: "As Covid-19 Vaccines Roll Out, States to Determine Who Gets Shots First" (December 9, 2020)

The Wall Street Journal: "U.S. Expects to Immunize 100 Million High-Risk People by End of February, Officials Say" (December 2, 2020)

Optum Rx: "Latest information on COVID-19 vaccines" (December 3, 2020)

Forbes: "How Employers Should Prepare For The Covid-19 Vaccine" (November 19, 2020)



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