

UNDERSTANDING COVID-19 VACCINES

Helping clients plan their vaccination strategies

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Express Scripts works hard, every day, to be your trusted partner and champion for better health care. As we face the COVID-19 pandemic together, our mission has never been more important. Use this resource to stay informed on how Express Scripts is addressing COVID-19.

As we step closer to widespread availability of the vaccine, Express Scripts recognizes the variables plan sponsors need to consider, such as:

- ▶ Availability of vaccine
- ▶ How members fit into the phased rollout
- ▶ Vaccine costs
- ▶ What you can do now to prepare

When will a vaccine be available?

In the United States, There are multiple COVID-19 vaccines are under development, and in various stages of approval. The Pfizer and Moderna vaccine have both received FDA Emergency Use Authorization.

1. How will we know that a COVID-19 vaccine is both safe and effective?

Express Scripts looks to the FDA and CDC to determine these factors. As is our standard practice, Express Scripts will make available all therapeutics that have been approved by the FDA. We also monitor the latest guidance from leading public health organizations such as the CDC and others.

2. What is FDA Emergency Use Authorization?

FDA's Emergency Use Authorization (EUA) application is a pathway originally created during 9/11 to make sure that lifesaving therapies could be available more quickly than a full FDA review and approval can provide. This allows earlier treatment for vulnerable patients.

3. What are the differences between the leading vaccine candidates?

There are three main platforms that vaccine manufacturers are utilizing to develop their therapeutics. A central theme is that all vaccine candidates are focusing on developing immunity to the "s protein"- this is a component of the COVID-19 virus that is critical to allow itself to attach to receptors within our body and infect our cells. By developing vaccines that promote an immune response in our body against this specific protein, the available clinical trial data has shown encouraging results in preventing significant disease and/or transmission. Another different between the candidates is differing storage requirements which could vary from simple refrigeration to deep freezing. We will convey more details for if/when a vaccine is authorized for use.

4. Pfizer recently announced the effectiveness of their vaccine, what does effectiveness mean?

The preliminary phase 3 clinical trial data released by Pfizer demonstrating 95% vaccine efficacy is a positive first step. During the FDA review, they will evaluate all available trial data to determine the safety and efficacy of the vaccine. Based on their review, the Pfizer vaccine has been approved for emergency use. The vaccine has been made available to healthcare workers and long-term care facility residents before being made available to the general public. Pfizer's vaccine has specific cold storage requirements and as a result will be primarily distributed by sites that possess those capabilities (health systems, hospitals etc.).

5. Will the COVID-19 vaccine be available for children?

The current vaccine candidates are primarily being studied in adults, although some of the clinical studies are enrolling pediatric populations. Approximately 10.5% of COVID-19 infections occur in children. Once enough pediatric safety and efficacy data has been analyzed with specific COVID-19 vaccines, we will learn more regarding the potential use in children. The Pfizer vaccine has been approved for use on people 16 years and older. Until further clinical trials occur, and FDA approval is received children should receive their flu and other scheduled vaccines, wear masks, physically distance, and practice frequent hand washing.

Members should speak to their physician before making any healthcare decisions.

6. What is Express Scripts' strategy for the procurement, storage, and dispensing of a COVID-19 vaccine, when it is available?

At this point, there is no plan for Express Scripts to procure, store, or dispense the vaccine through the Express Scripts Pharmacy.

How will the vaccine be covered and how much will it cost?

The federal government is committed to providing the vaccine itself to the American public at no cost.

1. Will the vaccine be considered a preventive service waiving cost share for a member?

Any vaccine that receives FDA approval and is recommended by CDC, will be covered as a preventive service. But in order for Express Scripts to manage this COVID Vaccine with the pharmacy benefit, the client will need to be enrolled in the vaccine program.

2. Can a member obtain the vaccine from an out-of-network provider for no cost-share?

ESI does not have the ability to adjudicate an out of network claim. The member can be reimbursed for their vaccine cost by paying the cash price at the pharmacy, then submitting a paper claim. While we expect the cost of the serum to be \$0.00 initially when paid by the government, whether or not the pharmacy administration fee is covered will be determined by the client and may vary based on the client's line of business. The out of network fee, if the client has chosen to impose one, will be waived.

What can clients and their members do now?

It's important to continue encouraging employees to follow medical guidance to cover the mouth and nose with a mask when around others, avoid close contact with people who are sick, practice physical distancing of at least 6 feet, and wash hands often. These practices have definitively been shown to decrease the spread of COVID-19 and the flu. Get more information about these and other steps you can take to protect yourself and others from COVID-19.

1. What are the benefits of the flu vaccine during the pandemic?

It's important to stay vigilant against other illnesses like influenza, also known as the flu, which has similar symptoms to COVID-19. Express Scripts and the CDC recommends all persons aged ≥ 6 months who do not have contraindications get the flu vaccine, which is covered under your current vaccine program. Although the flu vaccine does NOT provide protection against COVID-19, protection against the flu may help health care professionals potentially rule out a flu diagnosis when examining patient symptoms. There is some associative data showing potentially a mild protective effect against COVID-19 for individuals who take the conventional flu vaccine (<https://www.scientificamerican.com/article/a-flu-shot-might-reduce-coronavirus-infections-early-research-suggests/>)

How will vaccines be distributed?

The CDC is making COVID-19 vaccination recommendations for the United States based on input from the Advisory Committee on Immunization Practices (ACIP). ACIP is a federal advisory committee comprised of medical and public health experts who develop recommendations on the use of vaccines in the civilian population of the United States. ACIP 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

Each U.S. state submitted to the CDC for approval a state-specific distribution plan. The U.S. federal government contracted with McKesson to distribute most of the vaccine candidates and supplies at the government's direction. This is different than the normal vaccine distribution process where healthcare entities (such as pharmacies) contract directly for vaccine distribution.

1. Who gets priority access to the vaccine?

Priorities will be outlined in state planning documents but the first phase of vaccinations are only being provided to healthcare personnel and long-term care facility residents. More details to follow.

2. Will the vaccine need to be given each year?

At this time, the answer is unclear. Viruses tend to mutate over time, plus we do not yet completely understand how long vaccinations may provide protection from COVID-19 infection. This is a matter that will continue to be studied by the medical and scientific community.

3. Will members be required to have a second dose of the vaccine to be considered vaccinated?

Some vaccines require an initial and booster shot in order to be effective. The booster shot will be required within a certain number of days after the initial vaccine. The administrator of the initial dose will be responsible for setting the member's appointment for the booster dose at the time of the initial dose.

Some vaccines currently in development and trials will not require a booster dose.

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