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COVID VACCINE UPDATE

In the coming weeks, pharmaceutical companies are expected to submit their COVID-19 vaccines for FDA approval under the Emergency Use Authorization (EUA).

What Is An Emergency Use Authorization (EUA)?

In a declared emergency, like a pandemic, the FDA may allow the use of unapproved medical products, or unapproved uses of approved medical products under an EUA. These uses can include the ability to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met. For instance, when there are no adequate, approved and available alternatives, an EUA can be issued.

Will Covid-19 Vaccines Be Available Under A EUA?

Yes. It is reasonable to expect that one or more COVID-19 vaccines will become available under EUA from the FDA by the end of 2020 or early 2021, with potential full FDA approval mid-2021. The earliest the vaccine would be in the supply chain is December 12, 2020. This is assuming FDA approval of Pfizer's vaccine on December 10, 2020. The FDA has released guidelines that must be met before a vaccine will receive a EUA, which includes at least a 50% reduction in the coronavirus infection.

In December 2020, the FDA will consider authorizing an emergency use of two vaccines made by Pfizer and Moderna. The current estimates project that no more than 20 million doses of each vaccine will be available by the end of 2020 with each product requiring two doses. As a result, the shots will be rationed in the early stages.

Who Will The Vaccine Be Distributed To First?

An influential government advisory panel convened on Tuesday, December 1, 2020 to answer one of the most pressing questions in the U.S. coronavirus outbreak: ***Who should be at the front of the line when the first vaccine shots become available?***

The independent, 15-member panel of outside scientific experts officially made a recommendation to the director of the Centers for Disease Control and Prevention on who should be consider priority to receive the vaccine. The recommendation was that frontline health care workers, long-term care resident and long-term care employees would be first in line for a vaccine.

About 2 million people are living in nursing homes and other U.S. long-term care facilities. Those patients and the staff members who care for them have accounted for 6% of the nation's coronavirus cases and a staggering 39% of the deaths, CDC officials say.

The advisory panel will meet again at some point to decide who should be next in line. Among the possibilities of the next in line to receive the vaccine include teachers, police, fire fighters and workers in other essential fields such as food production and transportation, the elderly and people with underlying medical conditions. Depending on how state officials apply the panel's recommendations, it could also encompass janitorial staff, food service employees and medical records clerks. *(Cont.)*

COVID VACCINE UPDATE

Who Will The Vaccine Be Distributed To First?(Continued)

HHS officials have said they will distribute initial doses to states based on population, and it's possible some states won't receive enough to cover all their health care workers and nursing home residents. It will be up to state authorities whether to follow the guidance on vaccine distribution and to make further, more detailed decisions if necessary. For example, whether to put emergency room doctors and nurses ahead of other health care workers if vaccine supplies are low.

If someone does not fall into one of those groups, the reality is they should expect to wait as the vaccine will probably not become widely available in the U.S. until spring of 2021.

How A New Vaccine Is Developed, Approved And Manufactured

Food and Drug Administration (FDA) sets rules for the three phases of clinical trials to ensure the safety of the volunteers. Research test vaccines with adults first.

PHASE 1

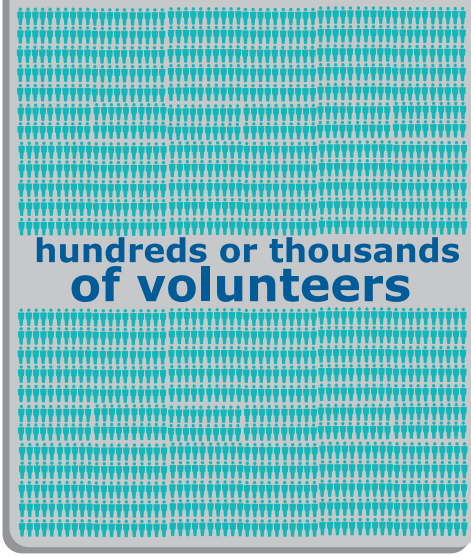
- Is this vaccine safe?
- Does this vaccine seem to work?
- Are there any serious side effects?
- How is the size of the dose related to side effects?

Source: Centers for Disease Control (CDC)

PHASE 2

- What are the most common short-term side effects?
- How are the volunteers' immune systems responding to vaccine

PHASE 3



- How do people who get the vaccine and people who do not get the vaccine compare?
- Is the vaccine safe?
- Is the vaccine effective?
- What are the most common side effects?

COVID VACCINE UPDATE

How A New Vaccine Is Developed, Approved And Manufactured(Continued)

Type	Product Name	Manufacturer	Route	Doses Required (Schedule)	Storage	Earliest Potential US Availability	Estimated Vaccine Cost*	Pros	Cons
Adenovirus Vector Vaccine	AZD1222	AstraZeneca	Intramuscular	2 (0, 28-42 days)	6 months at 36 - 46° F	1H 2021	$3-$4/ dose ($6-$8 for 2 dose regimen)	Robust immune response	Previous infection could limit immune response
RNA Vaccine	BNT162	Pfizer/BioNTech	Intramuscular	2 doses (0, 21 days)	**Freeze:** Ship and store up to 6 months at -94 to -112° F **Refrigerate:** Up to 5 days at 36 – 46° F **Room Temperature**: 2 hours	Mid to late December 2020	$20/dose ($40 for 2 dose regimen).	Rapid scalability/ Low cost production	Side Effect profile largely unknown.
RNA Vaccine	mRNA-1273	Moderna/NIAID	Intramuscular	2 doses (0, 28 days)	**Freeze:** Ship and store up to 6 months at -4° F **Refrigerate:** Up to 30 days at 36 - 46° F **Room Temperature:** 12 hours	Mid to late December 2020	$32-$37/ dose ($64-$74 for 2 dose regimen)	Rapid scalability/ Low cost production.	Side Effect profile largely unknown

**Does not include administrative fees*

There are three types of vaccines under development: RNA vaccines, traditional inactivated vaccines and adenovirus vector vaccines.

Inactivated Vaccines

These types of vaccines have a long history for being effective however, the ability to scale production and storage of these products poses difficulties. Inactivated vaccines are made from inactivated (or dead) virus. Injection of the inactivated virus mimic the viral infection and stimulates the body's immune response to produce antibodies.

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RNA Vaccines

These are RNA based vaccines, which contain messenger RNA (mRNA) that the body then translates to create proteins like that of the virus, called antigens. The body's immune system recognizes the antigens and then creates the antibodies needed to fight off the virus. While these new types of vaccines provide an opportunity to bring a product to market on a large scale with relatively low cost, the primary drawback is that they are still novel and there are many unknowns.

Pfizer and Moderna have completed phase 3 trials for a mRNA vaccine. For the Moderna vaccine, preliminary clinical trial data showed its vaccine was more than 94% effective. This vaccine is given two injections, four weeks apart. The vaccine remains stable at 36 to 46 degrees Fahrenheit, the temperature of a standard home or medical refrigerator, for up to 30 days. It can also be stored for up to six months at negative 4 degrees Fahrenheit.

Moderna expects to have roughly 20 million doses of its vaccine ready to ship to the U.S. by the end of the year (10 million total therapies since it does require 2 injections per patient). They remain on track to manufacture between 500 million to 1 billion doses globally in 2021.

The Pfizer vaccine is 90% effective in preventing coronavirus infections. This vaccine is given as two injections, 21 days apart. Unlike Moderna's vaccine, the Pfizer vaccine requires a storage temperature of minus 94 to minus 112 degrees Fahrenheit, including special storage equipment and transportation. This could make it very difficult for some countries to distribute.

Adenovirus Vector Vaccines

Adenovirus Vector vaccines leverage an existing virus that is altered to produce the SARS-CoV-2 protein. This process is intended to elicit an immune response to the virus. While the nature of this vaccine is anticipated to develop a more robust immune system response in patients, the drawback is that the immune response may not be effective among patients with existing robust immune systems, particularly those with prior adenovirus exposure.

What You As The Client Need To Know

During the initial phase of limited vaccine supply, the federal government will purchase all the initial supply of the vaccine and allocate vaccines to the states for prioritized distribution. During this time, the federal government will be covering the ingredient cost of the COVID-19 vaccine, however, plan sponsors will be required to cover the administration cost, with most plans requiring zero cost share to their plan members.

Current information would seem to indicate that the CARES Act requires that employer-sponsored and individual health plans subject to the ACA's preventive services standards cover a coronavirus vaccine without cost sharing 15 days after it is recommended by CDC's Advisory Committee on Immunization Practices (ACIP). (https://www.kff.org/report-section/vaccine-coverage-pricing-and-reimbursement-in-the-u-s-issue-brief/#endnote_link_496483-5) Confidio will continue to monitor CARES Act interpretations and provide updates as needed.

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What Is The Cost Of The Vaccine During The Initial Roll-Out Period?

Vaccine Administration Rates based on Medicare Fee-For-Service

- Multiple Dose Vaccine: **$16.94** for the first dose and **$28.39** for any subsequent dose.
- Single Dose Vaccines: **$28.39**

What Is The Current PBM Approach?

CVS:

- Opt-out strategy - CVS will add coverage of the COVID vaccine for all members unless client requests to opt out of coverage.

Express Scripts:

- Express Scripts will include coverage under their Pharmacy Vaccine Program. If a client is not enrolled in the vaccine program, the COVID vaccine will not be automatically added to coverage. For members to get a true $0 experience on ACA vaccines, clients must be enrolled in ESI's vaccine program, otherwise, the administrative fee cost will be passed to the member. Express Scripts is targeting to send client specific communications in early January.

MaxorPlus:

- Upon FDA approval, MaxorPlus will configure all plans in the adjudication system to allow for members to receive the COVID-19 vaccine at $0 cost share.

Optum:

- Should the vaccine be recommended for coverage under the ACA, the COVID vaccine will automatically be added to coverage for clients who cover preventive immunizations under the ACA.

WellDyne:

- WellDyne is participating in meetings with industry governing boards such as NCPDP providing access to the latest plans and details for vaccination administration. WellDyne's priority is to be fully prepared to support their clients and ensure member needs are thoroughly addressed. WellDyne expects to provide timely communication concerning additional details of vaccination administration plans.