UNDERSTANDING COVID-19 VACCINES

Helping You Plan Your Vaccination Strategies

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To help stop the global pandemic, the health care system needs to administer COVID-19 vaccines to 90% of the population. And we need to do it as quickly as possible to reduce the number of infections, prevent COVID-related deaths and enable a return to full social and economic activity. As we step closer to widespread availability of the vaccine, we at Express Scripts recognize there are several variables you need to consider. In addition to the questions below, you find additional tools in our Vaccine Guide for Plan Sponsors.

- COVID-19 vaccine availability, safety and effectiveness
- Plan costs and coverage
- Vaccine access for you and your members
- The role of Express Scripts and Evernorth in accelerating vaccine administration and distribution

JOHNSON & JOHNSON / JANSSEN VACCINE UPDATE

1. **What can you tell me about the six cases of blood clots reported in the news and why the FDA and CDC [temporarily] recommended a pause in the use of the J&J/Janssen COVID-19 Vaccine?**
   The J&J/Janssen vaccine is back on the market after a brief pause for FDA and CDC review. The pause occurred during April 12-23, 2021 and the review involved six cases (including one death) reported to the Vaccine Adverse Event Reporting System (VAERS) of rare types of blood clots in combination with low blood platelets, now referred to as thrombosis with thrombocytopenia syndrome. At the time of investigation, all cases occurred in females ranging in age from 18 through 48 years and involved blood clots in the large blood vessels of the brain (CVST). In some of the reported cases of CVST, blood clots also involved large veins in the abdomen.

   Out of an abundance of caution, the FDA and CDC recommended a pause in the use of the J&J/Janssen COVID-19 vaccine. However, after reviewing all available safety data, the CDC and FDA recommend use of this vaccine resume in the United States given that the known and potential benefits outweigh the known and potential risks.

   As of April 30th- there have been a total of 17 thrombotic events with thrombocytopenia reported with a total of 8-9m doses administered. This still is considered a very rare adverse event likely related to the Johnson and Johnson Vaccine.

2. **Why did the FDA and CDC make the decision to resume use of the J&J/Janssen COVID-19 Vaccine?**
   The CDC and FDA have recommended that use of J&J/Janssen COVID-19 Vaccine resume in the United States, effective April 23, 2021. A review of all available data at this time shows that the J&J/Janssen COVID-19 vaccine's known and potential benefits outweigh its known and potential risks in individuals 18 years of age and older.

The pause allowed CDC to communicate with healthcare providers and re-emphasize the importance of reporting severe events in people who have received this vaccine, as well as how to report such events. The pause also gave experts time to carefully review all available data and conduct a risk-benefit analysis around the use of this vaccine.

At this time, the available data suggest that the chance of this serious adverse event occurring is very low, but investigation into the level of potential excess risk due to vaccination is ongoing. For more information, review the latest J&J/Janssen updates on the CDC website, and the FDA's comprehensive Janssen COVID-19 Vaccine Frequently Asked Questions.

3. **Should those who recently received the J&J/Janssen COVID-19 Vaccine be worried?**
Right now, these adverse events appear to be extremely rare - occurring at a rate of about 1-2 per 1 million vaccinated individuals. While it appears that the majority of reported cases appeared to be women under the age of 50, it is still too early to tell whether this is accurate. The important thing to remember is that the risk of this adverse event is considered very rare. For now, people who have received the J&J vaccine and who develop severe headache, neurological symptoms such as weakness, abdominal pain, leg pain, or shortness of breath within three weeks after vaccination should contact their health care provider.

VACCINE AVAILABILITY, SAFETY AND EFFECTIVENESS

4. **What vaccines are currently available?**
In the United States, there are multiple COVID-19 vaccines being administered, under development, and in various stages of approval. Currently, there are two vaccines authorized and recommended to prevent COVID-19. Pfizer and Moderna received FDA Emergency Use Authorization (EUA) in December of 2020. Johnson and Johnson /Janssen was approved in February 2021 for EUA but is since being reevaluated (see question 1 for details). Additionally, we expect Novavax and AstraZeneca to be Issued FDA clearance as early as May 2021.

5. **What are the differences between the leading vaccines?**
There are basically three different platforms that manufacturers are utilizing to develop their vaccines: adenovirus-based, RNA-based or protein-based. Despite these differences, all vaccine candidates utilize a similar approach in promoting immunity by focusing on immunity to the "s protein." This is a critical component of the COVID-19 virus which allows itself to attach to receptors within our body and infect our cells. By developing vaccines that promote an immune response against this specific protein, the available clinical studies have shown excellent results in preventing significant disease, hospitalizations and death. The vaccines also have differing storage requirements which could vary from simple refrigeration to deep freezing.

6. **Pfizer and Moderna released data regarding the effectiveness of their vaccines. What does effectiveness mean?**
The preliminary phase 3 clinical trial data released by Pfizer and Modern demonstrated approximately 95% vaccine efficacy in preventing disease and 100% effective in preventing hospitalizations/death. Both vaccines have been authorized for emergency use by the FDA. The vaccine has been made available to healthcare workers and long-term care facility residents before being made available to the general public as part of a "phased-in" approach recommended by the CDC. Both vaccines have specific cold storage requirements and as a result will be primarily distributed by sites that possess those capabilities (health systems, hospitals etc.).

7. **How well do the vaccines protect against variants?**
New variants of the virus that causes COVID-19 are spreading in the United States. Current data suggest that COVID-19 vaccines authorized for use in the United States offer protection against most variants- particularly against hospitalization and death. However, some variants might cause illness in some people after they are fully vaccinated. For more information on how the vaccines are performing against the variants refer to the CDC website or our series Clinical Speaking with Dr. Wig.

8. **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.

PLAN COST AND COVERAGE

9. **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.

10. **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 Pharmacy Vaccination program.

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

    Yes. Express Scripts implemented a solution on 12/29/2020 to allow all pharmacies who are contracted to administer vaccines to be in-network for COVID-19 vaccinations, regardless of the client's chosen network for claims adjudication. This solution allows COVID-19 vaccines to adjudicate as in-network with no member disruption.

    To accommodate pharmacies that are not in any of our vaccine networks and allow them to submit claims for COVID-19 Vaccines, Express Scripts has created a special network for providers who do not want/ are not able to credential with Express Scripts. This special network will limit their ability to submit claims for ONLY COVID-19 Vaccines and will only be reimbursed a set Professional Service Fee of ($20.00) and dispensing fee. In order for a pharmacy to be included in this network, they must inform us of their ability to administer COVID-19 Vaccines. We will then add them to the network in 7-10 business days. Please note, that all contracting efforts with new pharmacies will be exhausted before using this option.

VACCINE ACCESS

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

12. **How will vaccines be distributed?**
    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.

    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. Initially, the ACIP recommended four groups for COVID-19 vaccination prioritization 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

    As of March 2, 2021, the Acting Secretary directed that teachers, school staff, and child care workers are eligible for COVID-19 vaccinations.

    As of May 1, 2021, all COVID-19 vaccination providers are directed and required to make available and administer COVID-19 vaccine to all persons eligible to receive the COVID-19 vaccine consistent with the applicable Emergency Use Authorizations for such products.

13. **Who gets priority access to the vaccine?**
    In late December 2020, the Advisory Committee on Immunization Practices recommended that health care personnel and residents of long-term care facilities be offered COVID-19 vaccine in the initial phase (1a) of the vaccination program.

- Phase 1b: Frontline essential workers and People age 75+; *Note: The Biden Administration has since followed-up strongly encouraging states to vaccinate those over age 65.*[1]
- Phase 1c: People age 65 – 74, People age 16 – 64 with high-risk medical conditions, and other essential workers
- Phase 2: 16 and above

However, given substantial increases in the supply of vaccines, the CDC has determined that it is appropriate to transition beyond priority groups and allow broad eligibility for receipt of COVID-19 vaccines consistent with applicable Emergency Use Authorizations.

14. Will the vaccine need to be given each year? Twice a year? Boosters?

At this time, the answer is unclear. Viruses tend to mutate over time, and 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.

15. 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. With Pfizer and Moderna, it is approximately 3-4 weeks after the first dose and full immunity is not achieved until 14 days after the second dose. 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. The Johnson & Johnson vaccine is a one-dose vaccine for individuals 18 and over, with full protection 28 days after vaccination.

16. Why are both does of the Pfizer-BioNTech and Moderna vaccine needed?

Getting both doses of these vaccines maximizes your ability to receive full immunity from the vaccine. Receiving only one dose does not provide you with the full protection against the disease and does not give you the full effectiveness of the vaccine.

17. Is the clinical edit in place now to ensure the first and second doses are from the same manufacturer? Are we doing anything proactively to members regarding communications on the 2nd dose?

Due to the State of Emergency, there are guardrails surrounding rules and edits that could have any potential to limit a member's ability to obtain a COVID-19 vaccine. Express Scripts has followed National Council for Prescription Drug Programs (NCPDP) guidelines in applying edits. We strongly recommend clients do not enter their own, until the State of Emergency ends. Any edit must be able to be overridden by the pharmacy, and edits cannot be entered for age or days allowed between initial and booster shot. Any edit requests must be reviewed prior to implementation to ensure both Express Scripts and our clients remain in compliance with federal guidelines and the CARES Act. For our part, we have approved and put two clinical edits in place:

- Edit to stop duplicate COVID-19 vaccine claims entered for the same member on the same day
- Safety edit to pause adjudication if the booster vaccine is not the same manufacturer as the member's initial vaccine

Starting in mid-February, Express Scripts began contacting members who obtained their first dose of the Pfizer or Moderna COVID-19 vaccine, via an automated outbound message (AOM), reminding them to schedule a follow-up appointment for the second dose (booster) of the COVID-19 vaccine if they hadn't already done so. The proactive, educational AOM will be placed within seven days of the member's first dose and will be triggered by a paid claim of the Pfizer or Moderna COVID-19 vaccine with an SCC of 02 (first dose) included on the claim.

Please note: Enrollment in the Pharmacy Vaccination program with a drug list that includes the COVID-19 vaccines is a prerequisite for members to receive the AOM. Vaccines obtained via the medical benefit will not be included within this AOM reminder campaign.

18. 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

[1] Tolbert, J. (21 Jan 2021). "The COVID-19 Vaccine Priority Line Continues to Change as States Make Further Updates." Kaiser Family Foundation.

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.

19. What can clients and their members do now?

Several states, counties and health systems are offering people the opportunity to pre-register for a vaccine. Members should check with their state and local health departments to understand the protocol in their area.

Clients interested in a COVID-19 vaccination clinic for members can start planning now. While supply is still not commercially available, we are actively expanding contracts to allow for both onsite pop-up clinics and vaccinations at offsite provider locations, including retail pharmacies. Clients can tell us their clinic needs and get more information at evernorth.com/vaccine.

It is also 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.

20. 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.[2] Also, fewer cases of the flu help reduce the strain on healthcare systems responding to the COVID-19 pandemic. Flu shots (and any other vaccines) should be separated by at least two weeks, per CDC recommendations.

EXPRESS SCRIPTS VACCINE ACCELERATION EFFORTS

21. Can Express Scripts help my employees get access to the vaccine?

Leveraging our deep relationships with retail pharmacies, labs and occupational health providers, we are actively working to bring you Evernorth COVID-19 Vaccination Clinics, once supply is commercially available. These clinics make it easy for you to protect your plan members through either dedicated onsite clinics or by reserving vaccinations offsite with a provider in your community. Take action so we can start preparations today.

22. 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.

[2] Moyer (27 Oct. 2020). "A Flu Shot Might Reduce Coronavirus Infections, Early Research Suggests." Scientific American.