COVID-19 Vaccines — Operational Considerations

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THE COVID-19 PANDEMIC HAS BROUGHT

many challenges to all areas of healthcare and the economy in general. The introduction of two vaccines in late 2020, from Pfizer and Moderna, begins the process to hopefully take control of the pandemic and enable life to return to normal. The timing of a return to normalcy is dependent upon many factors, including:

- The general population agreeing to be vaccinated.
- Minimal adverse reactions to the vaccines.
- The ability to supply vaccines for a large percentage of the population in a short time frame.
- Patients remembering and healthcare providers scheduling the second injection of the vaccine.
- Vaccinating a large percentage of the population to develop herd immunity to stop the spread of the virus.
- Effectiveness of the vaccines against mutated strains of COVID-19.

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PATIENT ACCEPTANCE

CVS Health recently conducted a study of the general population to assess people's willingness to be vaccinated. They reported the following population statistics:

- 28% were interested in a vaccine as soon as it is available.
- 35% would wait until others had been vaccinated.
- 20% were uncertain about receiving a vaccination.
- 17% did not plan on being vaccinated.

Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, predicts that between 70% and 85% of the population will need to be vaccinated before herd immunity is seen. Dr. Fauci also admits that no one really knows the correct percentage. The CVS Health study found that 37% of the population is uncertain or unwilling to be vaccinated. Education will be critical to changing this dynamic. The results seen in the prioritized populations, first responders, healthcare workers, and long-term care facility residents will be critical in demonstrating to a vast majority of the population that the vaccines are safe, with relatively few side effects. If this doesn't turn out to be the case, herd immunity will be difficult to attain.

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EMERGENCY USE AUTHORIZATION (EUA)

The FDA (Food and Drug Administration) states that an EUA is "a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. Under an EUA, the FDA may allow the use of unapproved medical products, or unapproved uses of approved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives. Taking into

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consideration input from the FDA, manufacturers decide whether and when to submit an EUA request to the FDA."

Both Pfizer and Moderna applied for and received an EUA from the FDA. Each vaccine requires two doses: the Moderna doses are spaced 28 days apart, whereas the Pfizer doses are 21 days apart. The Centers for Disease Control and Prevention (CDC) states that it takes a few weeks for the body to build immunity after vaccination. Therefore it is possible for a person to be infected with the COVID-19 virus right before or after vaccination because the vaccine has not had enough time to provide protection.

DISTRIBUTION CHALLENGES

Pfizer has designed temperature-controlled thermal shippers using dry ice to maintain recommended storage temperature conditions of minus 70 degrees Celsius for up to 10 days unopened. The Pfizer vaccine requires special freezers to store the vaccine at minus 70 degrees Celsius, with an estimated cost of $10,000, which would be an expensive investment to administer the Pfizer vaccine.

Moderna's vaccine will arrive in a shipping container, frozen at a temperature between minus 25 degrees Celsius and minus 15 degrees Celsius (minus 13 degrees and 5 degrees Fahrenheit) and verified with an internal temperature probe. This vaccine can be stored in a normal freezer but has a tight temperature range. The CDC recommends that "if storing the vaccine in a freezer with routinely recommended vaccines, carefully adjust the freezer temperature to the correct temperature range for this vaccine."

Finally, the AstraZeneca vaccine, which has *not* yet received an EUA by the FDA, does not require special freezers for storage. The price to the government is expected to be $4 per dose. Once an EUA is received, this vaccine should be able to be used in most pharmacies, as the storage requirements are similar to those for vaccines currently administered in retail pharmacies.

REIMBURSEMENT

The Coronavirus Aid, Relief, and Economic Security (CARES) Act provides funding from the federal government for the cost of the vaccine. Health plans and self-insured plans will be required to cover the administration cost of the COVID-19 vaccine. Administration fees for Medicare plans will be covered by Medicare fee-for-service, with the following rates:

- Administration cost for a two-dose vaccine: first dose $16.94; second dose $28.39.
- Administration fees for private insurers will be the subject of negotiation between plans and healthcare providers.

Based on a limited sample size, the average administration fee is approximately $20 for private insurers and health plans.

While there is no federal entitlement program for uninsured adults to receive vaccinations at no cost, under Section 317 of the Public Health Services Act, uninsured patients and those being vaccinated as part of a mass vaccination campaign are eligible to receive a limited number of vaccines purchased by the federal government. Reimbursement for the administration fee is not clear at this point. However, providing coverage for the uninsured is critical to achieving herd immunity.

BILLING GUIDANCE

Billing for vaccine administration fees under the pharmacy benefit is straightforward and similar to billing for flu vaccines. The difference is that the first two COVID-19 vaccines approved under the EUA require two doses. The National Council for Prescription Drug Programs (NCPDP) has issued guidance in a paper titled, "NCPDP Emergency Preparedness Guidance — COVID-19 Vaccines," which suggests the following:

For two-dose COVID-19 vaccines, use the liquid volume (e.g., 0.5 ml) for the quantity dispensed, a days' supply of "1," Professional Service Code "MA," ingredient cost of $0.00 or

The National Council for Prescription Drug Programs (NCPDP) guidance "NCPDP Emergency Preparedness Guidance — COVID-19 Vaccines" available here:

https://www.ncpdp.org/NCPDP/media/pdf/NCPDP-Emergency-Preparedness-Guidance-COVID-19-Vaccines.pdf

$0.01 depending on the payer, and the appropriate submission clarification code (SCC) indicating which dose in the series.

Initial dose — SCC of 2 "Other Override" defined as, "Used when authorized by the payer in business cases not currently addressed by other SCC values," to indicate the first dose of a two-dose vaccine is being administered.

Final dose — SCC of 6, "Starter Dose" defined as, "The pharmacist is indicating that the previous medication was a starter dose and now additional medication is needed to continue treatment," to indicate the final dose of a two-dose vaccine is being administered.

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Individual states are required to maintain electronic immunization registries to track which residents have received specific vaccines, when, and from what provider. Most vaccine providers connect their records directly to these state registries. The registries let providers determine which vaccine the patient needs if the initial vaccine dose was administered by a different provider.

NDC CODES — EUA AND COMMERCIAL PRODUCTS

All EUA vaccines are provided free of charge to patients. The Moderna vaccine approved for an EUA has NDC # 80777-0273-10. The Pfizer vaccine has NDC # 59267-1000-01. It is likely that once these vaccines receive FDA approval for commercial use, Moderna and Pfizer will begin charging for these products. Moderna and Pfizer should obtain different NDC numbers for the commercially approved products. The product code of the NDC (middle segment) and/or the package size identifier of the NDC (last segment) would be different from the EUA products.

Different NDCs will provide the means for proper claims submission, indicating the product that was used and allowing the healthcare provider to log the appropriate product in the patient's profile. This will also help to track and separate inventory of unapproved EUA vaccines and FDA-approved commercial products in the supply chain.

NEXT STEPS

Expect vaccine rollout tactics to change as knowledge is gained from patient reactions in the general population. Additional education requirements may be identified to ensure the second vaccine dose is received, and challenges with the supply chain or administration reimbursement may be uncovered as the rollout proceeds. Monitor your state and national pharmacy organizations for information and guidance to navigate the next few months.

Throughout the pandemic, it has been amazing to see public and private organizations come together to now enable pharmacists and healthcare providers to administer an estimated 460 million COVID-19 vaccine shots to 230 million Americans, which is a true testament to our healthcare industry. **CT**

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