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COVID-19 Vaccination, Treatment and Coverage under Workers' Compensation

A myMatrixx Position Paper

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IMPORTANT UPDATE to the myMatrixx Position Paper regarding COVID-19 Vaccination

- On April 7, 2021, President Joe Biden announced "that all U.S. adults should be eligible for Covid-19 vaccines by April 19." This announcement speeds up the previously announced goal of May 1st. Biden Says All U.S. Adults Should Be Eligible for Covid-19 Vaccine by April 19. - WSJ
- On February 27, 2021, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the third vaccine for the prevention of COVID-19. The EUA allows the Janssen COVID-19 Vaccine to be distributed in the U.S. for use in individuals 18 years of age and older. Janssen COVID-19 Vaccine | FDA
- However, **as of April 12**, more than 6.8 million doses of the Johnson & Johnson (Janssen) vaccine have been administered in the U.S. CDC and FDA are reviewing data involving six reported U.S. cases of a rare and severe type of blood clot in individuals after receiving the J&J vaccine. In these cases, a type of blood clot called cerebral venous sinus thrombosis (CVST) was seen in combination with low levels of blood platelets (thrombocytopenia). CDC will convene a meeting of the Advisory Committee on Immunization Practices (ACIP) on Wednesday to further review these cases and assess their potential significance. FDA will review that analysis as it also investigates these cases. Until that process is complete, we are recommending a pause in the use of this vaccine out of an abundance of caution. Joint CDC and FDA Statement on Johnson & Johnson COVID-19 Vaccine | CDC Online Newsroom | CDC
- Note: it is not possible to directly compare effectiveness of the three currently available vaccines because they clinical trials performed on each vaccine "occurred in different geographic regions and at different points in time with varying incidence of COVID-19." Janssen COVID-19 Vaccine Frequently Asked Questions | FDA
- Clinical trials are underway to examine Ofev (nintedanib) for severe respiratory illness caused by COVID-19. Ofev is already FDA approved for treat people with idiopathic pulmonary fibrosis (IPF). The new trial is a collaboration between the Icahn School of Medicine at Mount Sinai and Boehringer Ingelheim, the manufacturer of Ofev, based on clinical observations that "a significant percentage of COVID-19 patients with acute lung injury may develop lung fibrosis." Ofev Trial Enrolls 1st Patient With Post-COVID-19 PF (pulmonaryfibrosisnews.com) myMatrixx has already noted use of this drug among our patient population.
- Molnupiravir, developed by Merck and its partner Ridgeback Biotherapeutics, has completed phase 2 human clinical trials for COVID-19. This drug holds promise to decrease the length of infection from COVID-19 and has been described as similar to Tamiflu for influenza. Drug launched at Emory reduces virus that causes COVID-19 to undetectable levels. | Emory University | Atlanta, GA

Introduction

Workers' compensation has not traditionally paid for the cost of preventative care, including vaccinations, and it is expected that this will be the case for the majority of our clients regarding the COVID-19 vaccines. Any costs associated with the vaccine and its administration are expected to be covered by public or private insurance.

However, some clients have expressed concern over certain worker populations that may require vaccination, certain COVID presumption laws and other proposed regulations.

Currently, there is no cost for the vaccine itself. Vaccine doses purchased with U.S. taxpayer dollars will be given to the American population at no cost. However, vaccination providers will be able to charge an administration fee for giving the shot to someone. Vaccine providers can have this fee reimbursed by the patient's public or private insurance company or, for uninsured patients, by the Health Resources and Services Administration's Provider Relief Fund.

For comparison, Medicare payment rates for a COVID-19 vaccine requiring a series of two or more doses will be $16.94 for the initial dose(s) administration payment rate and $28.39 for the administration of the final dose in the series. These rates recognize the costs involved in administration of the vaccine, including the additional resources involved with required public health reporting, conducting important outreach and patient education, and spending additional time with patients answering any questions they may have about the vaccine. These rates will also be geographically adjusted.

Coverage for the administration fee under workers' compensation will be based on either a formulary process or prior authorization process that best serves a particular client or jurisdiction (refer to **Formulary Considerations** below).

It is important to note that none of the current vaccines are 100% effective, nor do they offer immediate immunity when they are effective. Therefore, individuals who receive the vaccination must still follow precautions such as social distancing and the use of masks (refer to **Additional Information Regarding COVID-19 Vaccines** below).

Formulary Considerations

Drug therapy for COVID-19 falls into three categories:

Prevention

Prevention involves the COVID-19 vaccines. myMatrixx recommends that coverage for the administration of the vaccine be handled through the prior authorization process on a case-by-case basis. We recommend that the vaccine only be added to a client's custom formulary if the client intends to pay for the administration of the vaccine for its entire population of workers.

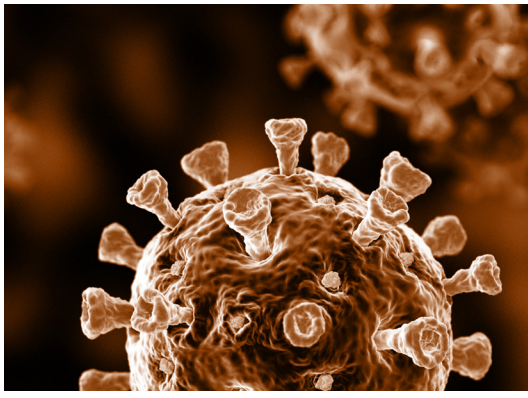
Supportive care

Supportive care involves the use of drugs that treat symptoms of COVID-19, but do not actually cure the patient. These drugs are not specific to COVID and treat a wide variety of conditions. Therefore, myMatrixx recommends that a COVID formulary only be implemented if it is expected that a large percentage of a client's workers may need immediate access to these drugs. Otherwise, we recommend the use of the prior authorization process.

Treatment

Most treatment drugs, such as remdesivir, are IV only and administered in hospital settings. Therefore, these drugs are not managed through the myMatrixx retail pharmacy network, and there is no corresponding impact to formularies or managed drug spend.

An individual may develop immunity from the vaccine, but it is unknown if the virus can still be carried and transmitted to others by a vaccinated (asymptomatic) individual.



Additional Information Regarding COVID-19 Vaccines

Efficacy Rates (post phase 3 clinical trials)

Pfizer 95% (One out of 20 not immune)

moderna 94.1% (1.18 out of 20 not immune)

janssen 72% following a single dose

94.1-95%
Vaccine efficacy

Approximately one out of every 20 individuals will not be immune after vaccination with the Pfizer or Moderna vaccines. That number is correspondingly higher with the 72% effectiveness rate of Janssen.

> *Johnson and Johnson has stated that clinical trials indicate the vaccine has an efficacy rate up to 72% following a single dose. It differs from the two current vaccines from Pfizer and Moderna in that it will not require refrigeration, making it much easier to distribute. The Differences Between the Pfizer, Moderna, and Johnson & Johnson Coronavirus Vaccines Explained | KQED*

Mechanism of Action

Pfizer and Moderna

- Known as an mRNA (messenger RNA) vaccine
- No live virus contained within the vaccine
- The mRNA teaches our immune cells to produce a protein spike, which will trigger antibody production

Janssen

- Known as a viral vectored vaccine, which is different from the messenger RNA vaccines produced by Pfizer and Moderna.
- Viral vectored vaccines utilize a harmless adenovirus that has been engineered to stimulate human cells to create antibodies against the SARS-CoV-2 virus.

Additional Information Regarding COVID-19 Vaccines cont.

Immunity

One inoculation (shot) of either the Pfizer or Moderna vaccines is not enough.

Only 50% immunity achieved after the first dose; second dose required 21 days later. Immunity is then realized only after seven days from the second inoculation. Therefore, individuals cannot expect immunity for four weeks following the start of the two inoculation series.

Second dose is required 28 days after the first dose. Immunity is then realized only after 14 days from the second inoculation. Therefore, individuals cannot expect immunity until six weeks following the start of the two inoculation series.

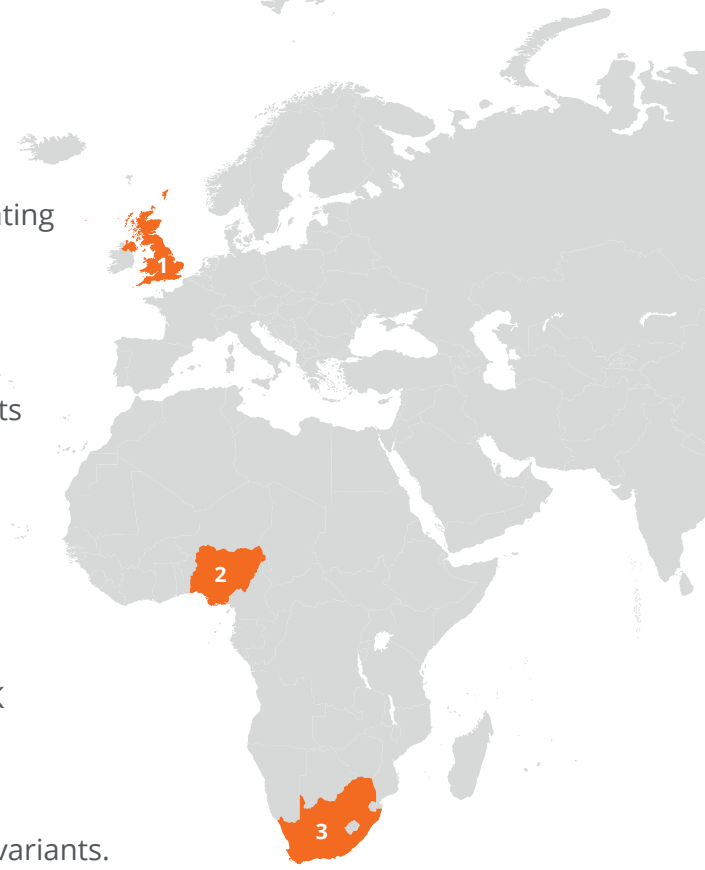
The CDC has released the following statement for individuals that did not or could not receive their second dose of either the Pfizer or Moderna vaccines as indicated: "**The second dose should be administered as close to the recommended interval as possible.** However, if it is not feasible to adhere to the recommended interval and a delay in vaccination is unavoidable, the second dose of Pfizer-BioNTech and Moderna COVID-19 vaccines may be administered up to 6 weeks (42 days) after the first dose. There are currently limited data on efficacy of mRNA COVID-19 vaccines administered beyond this window. If the second dose is administered beyond these intervals, there is no need to restart the series."

Side Effects of the Vaccine

- Usually only mild-to-moderate side effects
- Consist typically of mild flu-like symptoms
- Use with caution in patients on anti-coagulants
- Limited information available regarding use during pregnancy

New COVID Variants

There are multiple new variants of COVID currently circulating globally; notably three are being monitored by the CDC:



1 The United Kingdom variant
- Quickly mutates
- Spreads more quickly and easily than other variants

2 Nigerian variant
- Emerged recently
- Currently being monitored

3 South African variant
- Detected early October
- Emerged independently from the variant in the UK
- Also spreads easily and quickly

The CDC and other entities are currently evaluating the effectiveness of the COVID-19 vaccines for these new variants.

Herd Immunity

Herd immunity is dependent on the number of people in a population who receive the vaccine. This requires a large portion of a community to be vaccinated in order for herd immunity to develop.

According to Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, it is estimated that in order for the United States to return to pre-pandemic life by the end of 2021, 70 to 90 percent of the U.S. population must be vaccinated.

Availability of Vaccine

November 12, 2020: The Department of Health and Human Service and the Department of Defense announced partnerships with large chain pharmacies and networks that represent independent pharmacies and regional chains. Through the partnership with pharmacy chains, this program covers approximately 60 percent of pharmacies throughout the 50 states, the District of Columbia, Puerto Rico and the U.S. Virgin Islands. Through the partnerships with network administrators, independent pharmacies and regional chains will also be part of the federal pharmacy program, further increasing access to vaccine across the country, particularly in traditionally underserved areas. (https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html?language=en)

List of pharmacies available at https://www.hhs.gov/about/news/2020/11/12/trump-administration-partners-chain-independent-community-pharmacies-increase-access-future-covid-19-vaccines.html

Key Takeaways

- Continue to wear masks and practice social distancing even after receiving both doses of the vaccine
- The vaccine is not 100% effective
- There is no indication of how long immunity from the vaccine will last (indicators demonstrate that natural immunity may not last long)
- An individual may develop immunity from the vaccine, but it is unknown if the virus can still be carried and transmitted to others by a vaccinated (asymptomatic) individual

References for additional information

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https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

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Learn more about our Workers' Compensation products and solutions: **myMatrixx.com**

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