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NATIONAL AUTOMOTIVE ROADS FUEL ASSOCIATION

COVID-19 Vaccine Updates

Pfizer and Moderna COVID-19 Vaccine receive Emergency Use Authorization

Updated as of December 21, 2020

In less than one year since the identification of the SARS-CoV-2 virus, great progress has been made in the treatment and prevention of COVID-19 infections. To date, the FDA has granted Emergency Use Authorization (EUA) to two vaccines, one from Pfizer and the other Moderna, as well as multiple treatments for COVID-19 infections. The magnitude of these advances and speed at which they have occurred is remarkable. Below are some highlights:

Highlights

- On December 11, 2020, the FDA issued an EUA for the Pfizer COVID-19 vaccine followed by an EUA for the Moderna COVID-19 vaccine on December 18, 2020.
- Under the EUA, Pfizer's vaccine is authorized to be administered to people 16 years of age and older; while Moderna's vaccine is for people aged 18 years and older. At this time, there is insufficient data on the efficacy and safety of these vaccines in children.
- Both vaccines use a m-RNA platform and have reported upwards of 95% efficacy following a two- dose regimen and is consistent across age, gender, and ethnicity demographics in preventing infection. Vaccine immunity was measured 14 days after the second dose.
- A 2-dose regimen, either 21 days (Pfizer) or 28 days (Moderna) apart is required to achieve the efficacy rates identified in the studies. These vaccines are not considered interchangeable, so the CDC recommends the same manufacturer's vaccine be used for both doses.
- Distribution and administration of the vaccines began shortly following the EUAs with more than 128,000 people receiving the Pfizer vaccine within the first week of availability. Administration of the Moderna vaccine is expected to begin Monday, December 21, 2020.
- The CDC has recommended a phased approach to vaccine administration prioritizing select groups of people. The initial phase (Phase 1a) included healthcare workers and residents of long-term care facilities. Phase 1b will include front-line essential workers and adults aged 75 years and older which in total represents approximately 49 million people. The next group, or Phase 1c, includes adults aged 65 to 74 years of age, high-risk individuals 16-64 years and other essential works representing 129 million people.
- The majority of adverse effects reported following the administration of the vaccine have been mild to moderate and include symptoms such as injection site pain, fatigue, headache, muscle aches and fever. There have been reports of allergic reactions following the administration of the Pfizer vaccine which may be due to a component of the vaccine (polyethylene glycol).
- Clinical considerations have been given to select populations by the CDC:
  - Pregnant or breastfeeding patients: The vaccine has not been tested in pregnant individuals. The FDA recommends discussing potential benefits and risks of vaccination with their healthcare provider. Pregnancy is not an absolute contraindication.
  - HIV and immunocompromised patients: The FDA guidance recommends these patients can receive the vaccine if they do not have another condition for which vaccination is not advised.
  - Patients with prior SARS-CoV-2 infection: Data from clinical trials supports the use of the vaccine in this population

Considerations:

- As the EUA is temporary, both manufacturers will continue to gather additional data and prepare to file for full regulatory approval of their respective vaccines in 2021
- While the vaccines have demonstrated efficacy in preventing disease, more data is needed to better understand the vaccines' effect on preventing disease transmission
- Patients were followed for 7 weeks (Moderna), and 9 weeks (Pfizer) during clinical trials, so data about long term efficacy is lacking. As part of the EUA, both companies will continue to study trial participants and collect additional data related to vaccine induced immunity duration.
- There are several other vaccines including, but not limited to, Johnson & Johnson, AstraZeneca/University of Oxford, Merck, GSK/Sanofi and Novovax with the potential for EUA in 2021
- During the initial phases, the federal government will cover the ingredient cost of the COVID-19 vaccines. Per the Department of Health & Human Services, plan sponsors will need to cover the vaccine administration fee. The administration cost can be covered via the pharmacy or medical benefit. As the federal government has recently announced a partnership with several pharmacies, plans are encouraged to cover the administration fee under the pharmacy benefit. Most PBMs have negotiated administration fees between $17 and $29 per vaccination in the two-dose series.

https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid

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https://www.nytimes.com/interactive/2020/us/covid-19-vaccine-doses.html

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/COVID-02- Dooling.pdf

*Content comes courtesy of Cambridge Advisory Group