

Hot off the Press

Pfizer-BioNTech COVID-19 vaccine, first vaccine granted emergency use authorization (EUA) to prevent coronavirus disease 2019 (COVID-19)

News Alert:

- On December 11, 2020 Pfizer and BioNTech received United States (US) Food and Drug Administration (FDA) emergency use authorization (EUA) for the unapproved vaccine product Pfizer-BioNTech COVID-19 vaccine.
- This communication is preliminary based on information available at this time.

Highlights:

- First vaccine authorized in the US to prevent severe acute respiratory syndrome (SARS) coronavirus-2 (SARS-CoV-2) infection.
- Authorized use: active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals ≥ 16 years of age.
- Contraindicated in individuals with known history of severe allergy to any components of the vaccine.
- Vaccine platform: SARS-CoV-2 spike glycoprotein (S) antigen encoded by nucleoside-modified messenger RNA (mRNA) and formulated in lipid nanoparticles (LNPs).
- Dosage form: preservative-free frozen suspension for injection in a multidose vial; dilution is required.
- Dosing: Two 30 mcg doses administered intramuscularly 21 days apart.
- Authorization is based on an ongoing phase 3 trial that enrolled approximately 44,000 participants randomized to a 2-dose regimen of vaccine or placebo.
 - Efficacy for Pfizer-BioNTech COVID-19 vaccine in reported participants *without* prior COVID-19 infection was 95% measured ≥ 7 days after the second dose. Eight confirmed cases of COVID-19 were observed in the vaccine group compared to 162 cases in the placebo group.
 - In participants *with or without* prior COVID-19 infection, 94.6% vaccine efficacy measured ≥ 7 days after the second dose was observed, with 9 confirmed COVID-19 cases in the vaccine arm versus 169 cases in the placebo arm.
- Adverse reactions in clinical studies included injection site pain, fatigue, headache, muscle pain, chills, joint pain, fever, injection site swelling, injection site redness, nausea, malaise, and lymphadenopathy.
- Notably, 4 cases of Bell's palsy were reported in the vaccine group (none in placebo). Appendicitis was reported in 8 vaccine recipients and 4 placebo recipients. No causal relationship with either event has been determined.

- Safety and efficacy were generally consistent across age, gender, race, and ethnic populations. Systemic adverse reactions were more commonly reported after the booster than after the first dose; they were generally more frequent and severe in younger than older age groups.
- Pfizer-BioNTech COVID-19 vaccine is being studied in pediatrics ages ≥ 12 years.

Market Dynamics:

- Availability: Pfizer is coordinating vaccine distribution through United Parcel Service (UPS) and Federal Express (FedEx) and has already begun shipping vaccine doses. Initial supplies will be limited with an anticipated global supply of 50 million doses in 2020; up to 1.3 billion doses are expected by the end of 2021. Allocation within states is up to each state. The Centers for Disease Control and Prevention (CDC) recommends initial allocation be offered to front line healthcare workers and long term care facility residents and staff.
- Patient cost: The vaccine is free for all Americans without cost sharing.

Market Impact:

The COVID-19 pandemic has caused a public health crisis resulting in over 16 million confirmed cases in the US leading to approximately 300,000 deaths. Authorization for emergency use of Pfizer-BioNTech COVID-19 vaccine marks a critical and historic step toward combatting the pandemic, as the first COVID-19 vaccine in the US. The vaccine relies on genetic code to stimulate an immune response against COVID-19. The 2-dose regimen has resulted in 95% efficacy at least 7 days after the booster. Safety and efficacy are generally consistent across age, gender, race, and ethnic populations. Clinical trials assessing the safety and effectiveness of Pfizer-BioNTech COVID-19 vaccine are ongoing.

Pfizer-BioNTech COVID-19 vaccine requires ultra-cold chain process for distribution to ensure product stability. The vaccine must be stored at a temperature of $-70^{\circ}\text{C} \pm 10^{\circ}\text{C}$ and protected from light until ready to use. Pfizer is directly handling nationwide distribution of the vaccine using GPS and temperature-controlled thermal shippers to maintain this temperature when used with dry ice, which can also be used as a temporary storage for 30 days (if refilled with dry ice every 5 days). Once thawed, the vials can be stored for up to 5 days at standard refrigeration (2°C to 8°C). Vial contents must be used within 6 hours of dilution.

The federal government has already purchased vaccines which should be provided at no cost to individuals during the pandemic. Since initial supply will be limited for COVID-19 vaccines, the government has allocated supply based on states' populations. The CDC Advisory Committee on Immunization Practices (ACIP) recommends the Pfizer-BioNTech vaccine as authorized. Further, the CDC recommends allocating initial supplies to healthcare workers and long term care facility residents and staff as the first phase (phase 1a) priority group to receive COVID-19 vaccines.

On December 17, 2020, the FDA's Vaccines and Related Biological Products Advisory Committee will review data regarding Moderna's mRNA vaccine, mRNA-1273. The Moderna vaccine can be stored for 6 months in a standard freezer and at 30 days refrigerated. Additional investigational vaccines with more traditional cold chain requirements are under investigation.

Magellan Rx Management Action:

Magellan Rx Management continues to closely monitor the COVID-19 vaccine pipeline and provide clinical updates as appropriate.

References:

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- Polack FP, Thomas, SJ, Kitchin N, et al. Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. N Eng J Med. Published online December 10, 2020. DOI: 10.1056/NEJMoa2034577.
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