

Subject: FDA Authorizes Coronavirus (SARS-CoV2) Vaccine for Use

On December 11, 2020, the U.S. Food and Drug Administration (FDA) granted an emergency use authorization (EUA) for the first severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine for use in the U.S. The vaccine is a messenger RNA (mRNA) vaccine product co-developed by Pfizer and a German firm, BioNTech.¹ The EUA authorizes its use for the prevention of COVID-19 disease caused by SARS-CoV2 in individuals 16 years of age and older. This same vaccine, already authorized for use in five other nations (UK, Canada, Mexico, Saudi Arabia, and Bahrain), is being administered in early deployments in those nations. Additional authorizations, including the European Union, World Health Organization and other nations are expected in coming weeks.

A large number of other vaccines, some already authorized for use or progressing in clinical trials around the world, are also in pursuit of U.S. authorization and a number of those will approach the FDA to secure EUAs and further expand vaccine deployment in the U.S., including candidates from Moderna, Johnson & Johnson, Oxford/Astra Zeneca, and others.²

"An Emergency Use Authorization (EUA) is a mechanism available to FDA that facilitates the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic."³ Under an EUA, the FDA may allow the use of unapproved medical products to diagnose, treat, or prevent serious or life threatening diseases or conditions when certain statutory criteria have been met, including that there were no adequate, approved and available alternatives. The FDA must determine that the known and potential benefits outweigh the known and potential risks of the vaccine.³

The ongoing vaccine authorization process, scale up of production, challenging "cold chain" distribution requirements, and logistics of delivering vaccinations at a local level across the nation call for careful deliberation to deliver on the full promise of these as they come online. Recommending "who gets the first vaccines" has fallen to the Advisory Committee on Immunization Practices (ACIP), a panel of independent experts at the Centers for Disease Control and Prevention (CDC), who voted last week for health care workers at greatest risk of contracting COVID-19 and residents of nursing homes and long-term care facilities to be the first groups to receive vaccines.⁴ Next recommendations for additional groups will expand as vaccine availability grows. State, tribal, territorial, and local jurisdictions are working with the CDC to develop vaccination plans for their respective areas.

First Script will continue to monitor this situation and provide any updates relevant to the workers' compensation industry.

If you have any questions about this emergency use authorization, please contact your Account Manager, Account Pharmacist or email us at Ask The Pharmacist (askthepharmacist@cvty.us.com).

¹ U.S. Food and Drug Administration (FDA). FDA News and Events. Press Announcements. FDA Takes Key Action in fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine. Accessed at: <https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19>

² Regulatory Affairs Professional Society. News and Articles. Covid19 Vaccine Tracker. Accessed at: <https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker>

³ U.S. Food and Drug Administration (FDA). FDA News and Events. Press Announcements <https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained>

⁴ Centers for Disease Control and Prevention. COVID-19 (Coronavirus Disease). When Vaccine is Limited, Who Gets Vaccinated First? Accessed at: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations.html#:~:text=Who%20Gets%20Vaccinated%20First%3F,-Updated%20Dec.&text=Because%20the%20supply%20of%20COVID,long%2Dterm%20care%20facility%20residents.>