Image not found or type unknown

Workers' Comp

FDA Authorizes Pfizer/BioNTech COVID-19 Vaccine for Emergency Use

December 16, 2020
2 MIN READ

Mitchell International

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. 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 EUA's and further expand vaccine deployment in the US, including candidates from Moderna, Johnson & Johnson, Oxford/Astra Zeneca and others.

According to the FDA, “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.” 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.

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, 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. Next recommendations for additional groups will expand as vaccine availability grows. State, tribal, territorial and local jurisdictions are working with CDC to develop vaccination plans for their respective areas.

Mitchell Pharmacy Solutions will continue to monitor this situation and provide any updates relevant to the workers' compensation or auto casualty industries. If you have any questions about this alert, please contact your client services manager.

mitchell | genex | coventry