PHARMACY UPDATE

December 17, 2020

COVID-19 RELATED UPDATES

Disclaimer: We are receiving frequent COVID-19 related questions about drug concerns and potential interactions. This information is current as of December 17, 2020. We will do our best to keep you up to date with this ever-evolving situation.

Note: There are no Food and Drug Administration (FDA) approved therapies for treatment or prevention of COVID-19 in the outpatient setting or for prevention in the inpatient setting. Only remdesivir is FDA approved for treatment in the inpatient setting. If possible, it is best to have patients enrolled in a clinical trial when treating COVID outside of these parameters.

EMERGENCY USE AUTHORIZATIONS (EUA)

An EUA for a medication is authorized for the duration of the declaration unless the authorization is terminated or revoked sooner. Each EUA specifically defines the parameters for use of a given medication including indication and administration.

EMERGENCY USE AUTHORIZATION (EUA) FOR PFIZER-BIONTECH COVID-19 VACCINE (BNT162b2)

The FDA has issued an EUA to Pfizer and BioNTech's mRNA vaccine, BNT162b[1], for active immunization to prevent coronavirus disease 2019 (COVID-19) in individuals 16 years of age and older. It is a lipid nanoparticle–formulated, nucleoside-modified RNA vaccine that encodes a prefusion stabilized, membrane-anchored SARS-CoV-2 full-length spike protein. The EUA2 was granted based on data from an ongoing phase 3 multinational, placebo controlled, observer blinded, efficacy trial in approximately forty- four thousand study participants. The primary end points were efficacy of the vaccine against laboratory confirmed COVID-19 and safety. Study results showed that the vaccine was 95% effective ($p< 0.0001$) in people across age, gender, race and ethnicity demographics without prior severe SARS-CoV-2 and in those with or without evidence of infection before vaccination. With regards to safety, the vaccine was found to be well tolerated with no serious adverse events reported. There was insufficient data to grant EUA status to the following subpopulations: children under 16 years, pregnant or lactating women and immunocompromised individuals. The CDC Advisory Committee on Immunization Practices (ACIP) issued an interim clinical use recommendation on 12/12/2020 for the Pfizer-BioNTech COVID-19 vaccine.[3]

The Pfizer-BioNTech COVID-19 vaccine (30µg) is administered intramuscularly as a 2-dose series spaced 21 days apart. The preservative-free product is supplied as a multi-dose vial that contains 5 doses; the frozen suspension requires thawing and diluting prior to administration and must be used within 6 hours of dilution.

The state of Texas has been allocated 224,250 doses of the COVID-19 vaccine.[4] The state's expert vaccine allocation panel have determined that the first tier of vaccine recipients will include frontline hospital staff, long-term care staff working with vulnerable residents, emergency responders, home health care workers and residents of long-term care facilities. The second tier of recipients will include staff in outpatient care offices who interact with symptomatic patients, direct care staff in freestanding emergency sites and urgent care clinics, community pharmacy staff, public health and emergency response staff, "last responders" who provide mortuary or death services and school nurses.

1. Polack FP, Thomas SJ, Kitchin N, et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. N Engl J Med. Published online December 10, 2020. doi: 10.1056/NEJMoa2034577.
2. Pfizer and BioNTech receive FDA advisory committee vote supporting potential first emergency use authorization for vaccine to combat COVID-19 in the U.S. [press release]. New York, NY & Mainz, Germany; Pfizer, Inc and BioNTech SE; December 10, 2020.
3. Centers for Disease Control and Prevention. Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine.
4. "COVID-19 Vaccine Arrives in Texas." 14 Dec. 2020.

EMERGENCY USE AUTHORIZATION (EUA) FOR MODERNA COVID-19 VACCINE (mRNA-1273)

The FDA is reviewing an EUA to Moderna's mRNA vaccine, mRNA-12731, for active immunization to prevent coronavirus disease 2019 (COVID-19) in individuals 18 years of age and older at the time of writing this. It is a lipid nanoparticle–formulated, nucleoside-modified RNA vaccine that encodes a prefusion stabilized, membrane-anchored SARS-CoV-2 full-length spike protein. The EUA2 would be granted based on data from an ongoing phase 3 double-blinded placebo control trial with approximately 30,400 participants. The primary efficacy end point was the reduction of incidence of COVID-19 among participants without evidence of SARS-CoV-2 infections before the first dose of vaccine in the period beginning 14 days after the 2nd post-dose. Study results showed that the vaccine was 94.5% effective in people across age, gender, race and ethnicity demographics. With regards to safety, the vaccine was found to be well tolerated with no serious adverse events reported. There is anticipated to be insufficient data to grant EUA status to the following subpopulations: children under 18 years, pregnant or lactating women and immunocompromised individuals. The FDA Center for Biologics Evaluations and Research's (CBER), Vaccines and Related Biological Products Advisory Committee (VRBPAC) approved the Moderna COVID-19 vaccine on 12/17/2020 for EUA review. It is expected that the Moderna COVID-19 vaccine will be approved for the submitted EUA.

The Moderna COVID-19 vaccine (100 µg) is administered intramuscularly as a 2-dose series spaced 28 days apart. The preservative-free product is supplied as a multi-dose vial that contains 10 doses. Vials can be stored at refrigerated temps for up to 30 days prior to first use. After initial use, all doses in that vial must be used within 6 hours.

1. The FDA (17 December 2020). FDA Statement on Vaccines and Related Biological Products Advisory Committee Meeting.
2. in the First Interim Analysis of the Phase 3 COVE Study. Press Release 11/16/2020.
3. Centers for Disease Control and Prevention. Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine.

VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS) AND V-SAFE TOOL

With COVID-19 vaccination initiated under EUA, there is increased emphasis on reporting vaccine adverse effects for ongoing monitoring of any emerging safety concerns with wide-spread use of these new vaccines. In the United States a critical system for this reporting is the Vaccine Adverse Event Reporting System (VAERS).

Any vaccine adverse event may be reported through VAERS. However, certain reporting is mandatory. Per the Pfizer-BioNTech COVID-19 vaccine fact sheet for healthcare providers, the vaccination provider is responsible for the mandatory reporting to VAERS of any of the following: vaccine administration errors (even if not associated with an adverse event), any serious adverse event, any cases of Multisystem Inflammatory Syndrome (MIS) in adults or children and any cases of COVID-19 related hospitalization or death in vaccinated individuals.

Serious adverse events are defined as "death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, a congenital anomaly/birth defect, or an important medical event based on appropriate medical judgement that may jeopardize the individual and may require medical or surgical intervention to prevent" one of the previously list outcomes.[1]

How to report to VAERS? Phone: 1-800-822-7967, Online: https://vaers.hhs.gov/reportevent.html

For the Pfizer-BioNTech vaccine the report should specify "Pfizer-BioNTech COVID-19 Vaccine EUA"

Pfizer is requesting submission, when feasible, of adverse event reports to them either by contacting Pfizer directly or by submitting the VAERS reporting form to Pfizer (https://selfservehosteu.pfizer.com/pfrrdownload/file/fid/77056).

Individuals who receive the COVID-19 vaccine are going to be encouraged to utilize the Center or Disease Control's V-safe after vaccination health checker smartphone tool. It will allow communication with the CDC, through text messaging and web surveys, about any side effects and will provide individuals with a reminder when their second vaccine dose is due. More information on this tool can be found at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.[2]

1. Fact Sheet for Healthcare providers administering vaccine: emergency use Authorization (EUA) of the Pfizer-BioNTech COVID-19 vaccine to prevent coronavirus disease 2019. Accessed 12/15/2020 at https://selfservehosteu.pfizer.com/pfrrdownload/file/fid/77056
2. Centers for Disease Control and Prevention. V-safe after vaccination health checker. Accessed 12/15/2020 at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

GENERAL PHARMACY UPDATE

Disclaimer: This is the most update information at the time of publication. The General Pharmacy Update Newsletter section is providing these tips on lower cost alternatives to higher cost non-preferred prescription drugs. The key objective is to provide physicians with information. Ultimately, decisions about patient care, including prescriptions, are based on a physician's individual medical judgement.

ACCU-CHEK AVIVA METER DISCONTINUATION

The Accu-chek Aviva meter is being discontinued by the manufacturer. Test strips will continue to be available for a time. Providers may want to avoid writing for Accu-chek Aviva meters for new patients needing diabetic testing to avoid future availability issues.

1. https://www.accu-chek.com/meters/aviva-meter

For questions or concerns regarding information within this newsletter, Contact:
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