Arkansas Department of Health

4815 West Markham Street ● Little Rock, Arkansas 72205-3867 ● Telephone (501) 661-2000
Governor Asa Hutchinson
José R. Romero, MD, Secretary of Health

July 19, 2021

Re: Emergency Use Authorization (EUA) for the use of monoclonal antibody therapies for mild to moderate coronavirus disease 2019 (COVID-19)

Dear Colleagues

We are writing to you to provide some recent updates in the emergency use authorization (EUA) issued by the Food and Drug Administration (FDA) regarding monoclonal antibody therapies for COVID 19.

These monoclonal therapies have been shown to be highly effective when given early in disease course in preventing hospitalizations and emergency room visits in high-risk patients. In light of recent rapid increases in COVID-19 hospitalizations in Arkansas, using monoclonal antibody therapy to prevent patients from being hospitalized is critical at this time. Recent updates expand the definition of "high-risk" patients who are eligible for treatment and provide greater latitude to healthcare providers to exercise their clinical judgment. Clinicians may now refer any adult or pediatric (age 12 years and older and ≥40 kg) patient if they have a medical condition or other factor, including race/ethnicity, that puts them at higher risk for progressing to severe COVID-19, including:

- Older age (aged ≥65 years)
- Obesity (BMI >30)
- Diabetes
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung diseases (e.g., chronic obstructive pulmonary disease, moderate-to-severe asthma, interstitial lung disease, cystic fibrosis, pulmonary hypertension)
- An immunocompromising condition or immunosuppressive treatment (based on theoretic considerations, many experts strongly recommend therapy for patients who are immunosuppressed despite their limited representation in clinical trials).
- Overweight (BMI 25–30) as the sole risk factor
- Chronic kidney disease
- Pregnancy
- Sickle cell disease
- Neurodevelopmental disorders (e.g., cerebral palsy) or other conditions that confer medical complexity (e.g., genetic or metabolic syndromes and severe congenital anomalies)
- Medical-related technological dependence (e.g., tracheostomy, gastrostomy, or positive pressure ventilation [not related to COVID-19])

Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19 and authorization of REGEN-COV under the EUA is not limited to the medical conditions or factors listed above. See the EUA for more details.

Currently, there are 2 monoclonal antibody products available for treatment of COVID 19: REGEN-COV (distributed through US Health and Human Services [HHS]/Office of the Assistant Secretary for Preparedness and Response [ASPR]) and Sotrovimab. Distribution of bamlanivimab/etesevimab has been paused by ASPR on a national basis until further notice. In addition, FDA recommends that health care providers nationwide use alternative authorized monoclonal antibody therapies and not use bamlanivimab and etesevimab administered together at this time. Lab studies indicate that both REGEN-COV and Sotrovimab retain efficacy against the delta variant, which is main driver of the current rise in caseloads in Arkansas. Additional changes in the EUA for REGEN-COV allow for administration by intravenous infusion or subcutaneous injection.

At this time, we encourage all of you to discuss the option of monoclonal antibody therapy with patients in your practices. Subcutaneous injections can be utilized for delivery of REGEN-COV. REGEN-COV can be ordered free of charge. If you need assistance or guidance in setting up an account with Amerisource-Bergen please contact Elizabeth Woodland at Elizabeth.woodland@arkansas.gov.

Monoclonal antibody therapy may only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.

Other informational resources including locations where monoclonal antibody therapies are available through Arkansas and updates can be found on https://www.healthy.arkansas.gov/programs-services/topics/covid-19-guidance-about-monoclonal-antibodies

References

1. https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf
2. https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Sotrovimab/pdf/SOTROVIMAB-EUA.PDF#nameddest=HCPFS
3. https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-anti-sars-cov-2-monoclonal-antibodies-eua/