Arkansas Department of Health

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Governor Asa Hutchinson
José R. Romero, MD, Secretary of Health

Feb 4 2021

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

On Dec 18, The US Department of Health and Human Services (HHS) and Assistant Secretary for Preparedness and Response (ASPR) implemented a new federal program for the allocation of monoclonal antibodies called the Special Projects for Equitable and Efficient Distribution (SPEED).

The goal of SPEED is to assist states in identifying non-hospital/non-hospital affiliated facilities that serve priority populations - including nursing homes and federally qualified health centers (FQHCs) and allocating monoclonal antibodies (mAbs) for administration to their patients. It should be noted that SPEED is separate yet complementary to the state-based mAb allocation system.

The Arkansas Department of Health (ADH), working with the Arkansas Health Care Association (AHCA) has updated the guidance which should be followed when prescribing monoclonal antibodies for patients living in long term care facilities in Arkansas:

1. All sites **must** have a physician/physician assistant or an advanced practice nurse with a collaborative agreement with a prescribing physician who has examined the patient being evaluated for monoclonal antibody therapy
2. Sites **should** have a physician/physician assistant or an advanced practice nurse with a collaborative agreement with a prescribing physician on site at the time of administration of the infusion. However, if a provider is not available, infusions can occur if sites have adequately trained nursing staff to monitor patients during and at least 1 hour after the infusion
3. mAbs 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.
4. Health care providers must submit a report on all medication errors and **ALL SERIOUS ADVERSE EVENTS** potentially related to mAbs to FDA MedWatch.

LIMITATIONS OF AUTHORIZED USE

- These drugs are **not** authorized for use in patients who are hospitalized due to COVID-19, **or**
- who require oxygen therapy due to COVID-19, **or**
- who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.

The mAbs CAN be used for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization**. High risk is defined as patients who meet at least one of the following criteria:**

- Have a body mass index (BMI) ≥35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are ≥65 years of age
- Are ≥55 years of age AND have
  o cardiovascular disease, OR hypertension, OR chronic obstructive pulmonary disease/other chronic respiratory disease.
- Are 12 – 17 years of age AND have
  - o BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm, OR
  - o sickle cell disease, OR
  - o congenital or acquired heart disease, OR
  - o neurodevelopmental disorders, for example, cerebral palsy, OR
  - o a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR
  - o asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.

Of note; these infusions should NOT be used in ASYMPTOMATIC cases.

Sample order sheet with consent forms is attached and can be utilized by facilities.

For a complete list of the limitations of authorized use, mandatory requirements for the administration, dosing, storage, warnings, side effects, and the full EUA for the prescribing information can be found in the attached documents.

Links to additional documents are located below.

EUA for Bamlanivimab - https://www.fda.gov/media/143603/download
Patient Fact Sheet - https://www.fda.gov/media/143604/download
FDA Frequently Asked Questions - https://www.fda.gov/media/143605/download

EUA for Casirivimab and Imdevimab - https://www.fda.gov/media/143892/download
Patient Fact Sheet - https://www.fda.gov/media/143893/download
FDA Frequently Asked Questions - https://www.fda.gov/media/143894/download

FDA MedWatch: www.fda.gov/medwatch/report.htm