Arkansas Department of Health

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

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

On Nov 9, the U.S. Food and Drug Administration (FDA) issued an EUA to permit the emergency use of the unapproved product bamlanivimab (manufacturer Eli Lilly) 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.

On Nov 21, FDA issued another EUA to permit the emergency use of the unapproved products casirivimab and imdevimab (manufacturer Regeneron) to be administered together for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID19 and/or hospitalization.

The U.S. Department of Health and Human Services is allocating initial doses of these investigational monoclonal antibody to state health departments free of cost to be distributed within their territories.

Arkansas Department of Health, working in collaboration with the Arkansas Hospital Association has identified sites for administration of these monoclonal antibodies; and will be providing the medication to these locations.

Bamlanivimab and the combination of casirivimab and imdevimab 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.

These government-purchased doses will be available at no cost to patients, although healthcare facilities could charge for administering the medicine – as is customary with such government-purchased products.

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.

- Benefit of treatment with monoclonal antibodies has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

This EUA is for the use of the unapproved product bamlanivimab and the combination of casirivimab and imdevimab 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
  - BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm, OR
  - sickle cell disease, OR
  - congenital or acquired heart disease, OR
  - neurodevelopmental disorders, for example, cerebral palsy, OR
  - a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR
  - asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.

Individual administration sites may have additional criteria for use of these monoclonal antibody therapies in patients. Providers are encouraged to contact sites directly for additional information if they have patients who may benefit from this therapy and meet the criteria set by FDA and the entity administering the infusion.

The following locations have been identified as sites for administration and will be updated weekly.

CHI ST VINCENT HSP HOT SPRG IP
ACMC-CROSSETT
ARKANSAS CHILDRENS HOSPITAL PHCY
ARKANSAS HEART HOSPITAL
ARKANSSAS METHODIST MED CTR
BAPTIST HEALTH FORT SMITH
BAPTIST HEALTH MED CTR CONWAY
BAPTIST HEALTH MED CTR HEBER SPR
BAPTIST HEALTH MED CTR NLR
BAPTIST HEALTH MED CTR STUTTGART
BAPTIST HLTH MED CTR ARKADELPHIA
BAPTIST HLTH MED CTR LITTLE ROCK
BAPTIST MEM HOSP NEA
BAPTIST MEMORIAL HOSPITAL-WEST MEMPHIS
BAXTER REG MED CTR
CHI ST VINCENT HSP HOT SPRG IP
CRMC, INC WAC
CROSSRIDGE COMM HOSP
DEWITT HOSP AND NURSING HOME
GREAT RIVER MEDICAL CENTER
JEFFERSON REG MED CTR
JOHNSON REG MED CTR
MCGEHEE HOSPITAL,INC
MED CTR SOUTH ARKANSAS-UNION
MERCY HOSP BERRYVILLE
MERCY HOSP FORT SMITH
MERCY HOSP NW ARKANSAS
NARMC PHARMACY DEPT-HARRISON
NATIONAL PARK MED CTR
NORTHWEST MEDICAL CTR OF BENTON CO
NW HLTH PHCYSICIANS SPCLTY HOSPITAL
OUACHITA CNTY MED CTR
OZARK COMMUNITY HOSP-GRAVETTE
OZARK HEALTH HOSPITAL PHARM
SALINE MEMORIAL HOSPITAL
ST BERNARDS REG MED CTR
ST MARYS REGIONAL MED CTR
ST VINCENT INFIRMARY MED CTR
STONE COUNTY MED CTR
UAMS
WASHINGTON REG MED CTR

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