

# Missouri Department of Health & Senior Services

## Health Update:

### Update: Indications for Monoclonal Antibodies in Management of COVID-19

September 15, 2021

This document will be updated as new information becomes available. The current version can always be viewed at <http://www.health.mo.gov>.

The Missouri Department of Health & Senior Services (DHSS) is now using four types of documents to provide important information to medical and public health professionals, and to other interested persons:

**Health Alerts** convey information of the highest level of importance which warrants immediate action or attention from Missouri health providers, emergency responders, public health agencies or the public.

**Health Advisories** provide important information for a specific incident or situation, including that impacting neighboring states; may not require immediate action.

**Health Guidances** contain comprehensive information pertaining to a particular disease or condition, and include recommendations, guidelines, etc. endorsed by DHSS.

**Health Updates** provide new or updated information on an incident or situation; can also provide information to update a previously sent Health Alert, Health Advisory, or Health Guidance; unlikely to require immediate action.

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September 15<sup>th</sup>, 2021

**FROM: DONALD KAUEAUF, DHSS DIRECTOR**

**SUBJECT: Update: Indications for Monoclonal Antibodies in Management of COVID-19**

**As of July 30, 2021, FDA has authorized post-exposure prophylaxis (PEP) use of the COVID-19 monoclonal antibody therapeutic REGEN-COV (casirivimab and imdevimab). REGEN-COV is expected to be effective against circulating variants, including the Delta variant, and is authorized for outpatient treatment of patients with COVID-19. As of August 27, 2021, the FDA has reinstated bamlanivimab and etesevimab administered together for use only in states with low combined frequency of resistant variants. The bamlanivimab and etesevimab administered together are currently authorized for treatment in Missouri. Recent updates to the Emergency Use Authorizations (EUA) for COVID-19 monoclonal antibodies by the FDA also expanded the definition of “high-risk” outpatients 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  $\geq 40$  kg) outpatient for monoclonal antibody treatment if they have a medical condition or other factor, including race/ethnicity, that puts them at higher risk for progressing to severe COVID-19. Early testing, identification, and referral are vital for outpatient monoclonal antibody treatment.**

Monoclonal antibodies (mAbs) directly neutralize the COVID-19 virus and are intended to prevent progression of disease. The mAbs are most effective when given early in infection. Evolving evidence demonstrates usefulness of mAb products in outpatient settings. Evidence from Eli Lilly mAb cocktail (bamlanivimab and etesevimab) trials showed potential to reduce hospitalization and death in infected people if given early in infection. Data from Regeneron mAb cocktail trial showed potential to decrease viral load and reduced medical visits in infected people if given early.

On August 27, 2021, the FDA reinstated the authorized use of [bamlanivimab and etesevimab administered together under Emergency Use Authorization \(EUA\) 094](#). Bamlanivimab and etesevimab are authorized for use only in states, territories, and U.S. jurisdictions in which the combined frequency of variants resistant to bamlanivimab and etesevimab administered together is less than or equal to 5%, as determined by FDA. The Centers for Disease Control and Prevention (CDC) determined that the [frequency of the SARS-CoV-2 B.1.617.2/Delta variant \(first identified in India\)](#) is increasing throughout the U.S. and has become the dominant variant in the US. Based on in vitro assays that are used to assess the susceptibility of viral variants to monoclonal antibodies, bamlanivimab and etesevimab, administered together, **are** expected to retain activity against the Delta variant (B.1.617.2). Based on these in vitro assays, bamlanivimab and etesevimab, administered together, **are not** expected to retain activity against the SARS-CoV-2 P.1/Gamma variant (first identified in Brazil), the B.1.351/Beta variant (first identified in South Africa), the AY.1 and AY.2 variants/Delta[+K417N] (commonly known as “Delta plus,” first identified in India) and the B.1.621 variant (first identified in Colombia). With the emergence of the B.1.617.2/Delta variant as the dominant variant in the U.S., the frequency of identified variants expected to be resistant to bamlanivimab and etesevimab administered together is steadily decreasing.

Based on the above, bamlanivimab and etesevimab administered together are currently authorized for use in Missouri (list of states, territories and U.S. jurisdictions in which bamlanivimab and etesevimab are and are not currently authorized is available on FDA’s website at:

<https://www.fda.gov/media/151719/download>).

ASPR has resumed distribution of bamlanivimab and etesevimab together and etesevimab alone (to pair with existing supply of bamlanivimab at a facility for use under the EUA).

Considering similar in vitro assay data currently available, REGEN-COV and sotrovimab are likely to retain activity against the P.1, B.1.351, AY.1 and AY.2, B.1.621, and B.1.617.2/Delta variants. As such, the use and distribution of REGEN-COV and sotrovimab are not impacted by the circulating variants based on information available at this time. All treatment delivery sites can continue ordering REGEN-COV from the authorized distributor by following the existing ordering and reporting procedures. All treatment sites may also find information on the [availability and ordering of sotrovimab](#) by visiting GlaxoSmithKline’s [website](#).

### **Current Indications for Monoclonal Therapy & Appropriate mAbs for Treatment**

Post-Exposure Prophylaxis (PEP) in vulnerable persons (i.e. not fully vaccinated or immunocompromised) who are at high risk for progression to severe COVID-19

- *REGEN-COV* (casirivimab and imdevimab)

Active COVID-19 Infection in high risk individuals with mild to moderate symptoms

- *REGEN-COV* (casirivimab and imdevimab)
- *Bamlanivimab/Etesevimab*

- *Sotrovimab*

### **Eligibility for Post-Exposure Prophylaxis**

REGEN-COV (casirivimab and imdevimab) is authorized for post-exposure prophylaxis of COVID-19 in individuals who are:

- Adult or pediatric (> 12 years of age and weighing at least 40kg) patient at high risk for progressing to severe disease or death
- Not fully vaccinated or who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications) AND
  - have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per CDC, OR
  - who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of COVID-19 in other individuals in the same institutional setting (for example, nursing homes, prisons)

#### Limitations of Authorized Use:

- PEP with REGEN-COV (casirivimab and imdevimab) is not a substitute for vaccination against COVID-19
- REGEN-COV (casirivimab and imdevimab) is not authorized for pre-exposure prophylaxis for prevention of COVID-19

### **Eligibility for Treatment of Mild-Moderate Covid-19 Infection in High Risk Individuals**

Monoclonal antibodies granted EUA for mild to moderate COVID-19 cases early in infection, who are at high risk for progressing to severe COVID-19 and/or hospitalization with following criteria:

- Adult or pediatric (> 12 years of age and weighing at least 40kg) patient
- Confirmation via positive PCR or antigen test
- Treatment as soon as possible following positive viral test and within 10 days of symptom onset
- Patient symptomatic but not yet progressed to require hospitalization or oxygen therapy (or increase from baseline chronic oxygen therapy)

#### **HIGH RISK FACTORS INCLUDE, BUT ARE NOT LIMITED TO:**

- Older age (for example > 65 years of age)
- Obesity or being overweight (for example, adults with BMI > 25, or if age 12-17, have BMI > 85th percentile for their age and gender based on CDC growth charts)

- Pregnancy
- Chronic Kidney Disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis, and pulmonary hypertension)
- Sickle cell disease
- Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital abnormalities)
- Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19

Eligibility is not limited to the medical conditions and factors listed above. For additional information on medical conditions and factors associated with increased risk for progression to severe COVID-19, see the CDC website: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>

### **How to Find Infusion Locations**

Further information about monoclonal antibody infusions and where to access this treatment in Missouri is located at: <https://health.mo.gov/living/healthcondiseases/communicable/novel-coronavirus/monoclonal-antibody-treatment.php>

Specific information about each site, their referral procedures and location is available by clicking on the thumbtack for the site on the map.

**Missouri healthcare providers and public health practitioners: Please contact your Local Public Health agency or the Missouri Department of Health and Senior Services' (DHSS') Bureau of Communicable Disease Control and Prevention at 573-751-6113 or 800-392-0272 (24/7) with questions regarding this Health Advisory.**