Health Advisory:

SARS-CoV-2 Monoclonal Antibody Treatment Update

Date July 27, 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, and/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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FROM: **Robert Knodell, DHSS Acting Director**

SUBJECT: **SARS-CoV-2 Monoclonal Antibody Treatment Update**

The Missouri Department of Health and Senior Services (DHSS) is providing this updated advisory regarding monoclonal antibody treatment for COVID-19. Previously, DHSS issued a Health Advisory on April 13, 2021 about such treatment options. The April 13 health advisory detailed Eli Lilly's bamlanivimab and bamlanivimab plus etesevimab combo. Since then, U.S. health officials have paused the distribution of those two Eli Lilly & Co. Covid-19 monoclonal antibody treatments because of data showing that they aren't effective against virus variants that are common across the country. There are two remaining options for monoclonal antibody based treatment, each exists under an Emergency Use Authorization, Regeneron's product consisting of casirivimab and imdevimab, and GSK's sotrovimab.

Each treatment has similar emergency use and restriction guidance:

- for the treatment of mild-to-moderate coronavirus disease 2019 (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 progression to severe COVID-19, including hospitalization or death.

Each product is 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).

To date, each treatment has been indicated to be effective against known COVID-19 causing SARS-CoV2 variants in circulation, including the Delta variant.

Full details on the EUA for GSK's sotrovimab are found at https://www.fda.gov/media/149534/download and EUA information for Regeneron's casirivimab and imdevimab is at https://www.regeneron.com/downloads/treatment-covid19-eua-fda-letter.pdf.

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.