

MESSAGE ID: MSHAN-20210802-00529-ALT (Health Alert)

RECIPIENTS: All Physicians, Hospitals, ERs, ICPs, NPs, and Healthcare Providers –

Statewide

Monday, August 2, 2021

SUBJECT: Monoclonal Antibody Update for COVID-19: Subcutaneous Use and

Emergency Use Authorization for Post-Exposure Prophylaxis

The Mississippi State Department of Health recognizes the importance of monoclonal antibodies (mAbs) for the early treatment of COVID-19 in patients at high risk for developing severe disease and/or hospitalization.

• mAbs can be utilized in patients regardless of vaccination status

- mAbs can be used for treatment in a second COVID-19 infection
- REGEN-COV has been purchased by the U.S. Government and is no cost to you or your patient
- The patient eligibility criteria in the drugs' Emergency Use Authorizations (EUA) were expanded and allow for your discretion if your patient is determined to be high risk for progressing to more severe disease, such as ≥ 65 years of age, obesity, pregnancy, chronic kidney disease, immunosuppression, or other medical conditions or factors (for example race or ethnicity) that may place individual patients who are >12 years of age at high risk for progression to severe disease. Use of mAb therapy is based on evidence that supports your clinical judgment. See the EUA below for full details.
- Also please note that **these can now be given sub-cutaneous.** FDA Authorizes Lower 1,200 mg Intravenous and Subcutaneous Dose of REGEN-COVTM (casirivimab and imdevimab) Antibody Cocktail to Treat Patients with COVID-19 | Regeneron Pharmaceuticals Inc.
- Use this tool to assist in determining if your patient is high risk and where to refer them to for treatment
 - Referral Information for Monoclonal Antibody Treatment (COVID-19 Centers of Excellence) - Mississippi State Department of Health (ms.gov)

UPDATE: The REGEN-COV Emergency Use Authorization (EUA) has been expanded to include post-exposure prophylaxis.

The new authorization is for post-exposure prophylaxis use:

- *in adult and pediatric individuals* (12 years of age and older weighing at least 40 kg) for post-exposure prophylaxis of COVID-19 in individuals who are at *high risk for progression to severe COVID-19*, including hospitalization or death, *and* are:
- 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 because of occurrence of COVID-19 infection in other individuals in the same institutional setting (for example, nursing homes or prisons)
- REGEN-COV is expected to be effective against circulating variants, including the Delta variant. It should be noted that post-exposure prophylaxis with REGEN-COV is not a substitute for vaccination against COVID-19, and REGEN-COV is not authorized for pre-exposure prophylaxis.

The monoclonal antibodies currently available are REGEN-COV (Regeneron) and sotrovimab (GlaxoSmithKline). **Bamlanivimab/etesevimab (Eli Lilly) is on a nationwide pause at this time.** Please note that the EUAs for these drugs can be updated frequently.

treatment-covid19-eua-fact-sheet-for-hcp.pdf (regeneron.com)

SOTROVIMAB-EUA.PDF (gskpro.com)

If you have questions about the monoclonal antibodies, please email <u>Elisabeth.Smith@msdh.ms.gov</u>

Alerting Message Specification Settings

Originating Agency: Mississippi State Department of Health

Alerting Program: MS Health Alert Network (MS HAN)

Message Identifier: MSHAN-20210802-00529-ALT

Program (HAN) Type: Health Alert

Status (Type): Actual ()

Message Type: Alert

Reference: MSHAN-00529

Severity: Unknown

Acknowledgement: No

Sensitive: Not Sensitive

Message Expiration: Undetermined

Urgency: Undetermined

Delivery Time: 600 minutes

Definition of Alerting Vocabulary and Message Specification Settings

Originating Agency: A unique identifier for the agency originating the alert.

Alerting Program: The program sending the alert or engaging in alerts and

communications using PHIN Communication and Alerting (PCA)

as a vehicle for their delivery.

Message Identifier: A unique alert identifier that is generated upon alert activation

(MSHAN-yyymmdd-hhmm-TTT (ALT=Health Alert, ADV=Health Advisory, UPD=Health Update,

MSG/INFO=Message/Info Service).

Program (HAN) Type: Categories of Health Alert Messages.

Health Alert: Conveys the highest level of importance; warrants immediate

action or attention.

Health Advisory: Provides important information for a specific incident or situation;

may not require immediate action.

Health Update: Provides updated information regarding an incident or situation;

unlikely to require immediate action.

Health Info Service: Provides Message / Notification of general public health

information; unlikely to require immediate action.



Status (Type):

Actual: Communication or alert refers to a live event Exercise: Designated recipients must respond to the

communication or alert

Test: Communication or alert is related to a technical, system test and should be

disregarded

Message Type:

Alert: Indicates an original Alert

Update: Indicates prior alert has been Updated and/or superseded

Cancel: Indicates prior alert has been cancelled Error: Indicates prior alert has been retracted

Reference: For a communication or alert with a Message Type of "Update" or "Cancel", this attribute contains the unique Message Identifier of the original communication or alert being updated or cancelled. "n/a" = Not Applicable.

Severity:

Extreme: Extraordinary threat to life or property
Severe: Significant threat to life or property
Moderate: Possible threat to life or property
Minor: Minimal threat to life or property
Unknown: Unknown threat to life or property

Acknowledgement: Indicates whether an acknowledgement on the part of the recipient is required to confirm that the alert was received, and the timeframe in which a response is required (Yes or No).

Sensitive:

Sensitive: Indicates the alert contains sensitive content

Not Sensitive: Indicates non-sensitive content

Message Expiration: Undetermined.

Urgency: Undetermined. Responsive action should be taken immediately.

Delivery Time: Indicates the timeframe for delivery of the alert (15, 60, 1440,

4320 minutes (.25, 1, 24, 72 hours)).