MISSISSIPPI STATE DEPARTMENT OF HEALTH

This is an official
MS Health Alert Network (HAN) Alert

MESSAGE ID: **MSHAN-20220126-00553-ALT (Health Alert)**

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

Wednesday January 26, 2022

SUBJECT: **COVID-19 Therapeutics-UPDATES-Use of REGEN-COV and Bamlanivimab/Etesevimab No Longer Authorized by FDA; Remdesivir Approved for Outpatient Treatment**

Dear Colleagues,

UPDATES

- **On January 24, 2022, the FDA released a statement indicating that the monoclonal antibodies REGEN-COV and Bamlanivimab/Etesevimab are no longer authorized for use in any U.S. state due to the growing proportion of Omicron variant these treatments are not effective against. (See Coronavirus (COVID-19) Update: FDA Limits Use of Certain Monoclonal Antibodies to Treat COVID-19 Due to the Omicron Variant | FDA for the full communication).**
  a. **MSDH is no longer recommending the use of REGEN-COV or Bamlanivimab/Etesevimab in Mississippi and will no longer distribute further doses.**
  b. **Providers that have these monoclonal antibodies on hand are encouraged to retain this product in the event of the emergence of a variant strain these prove to be effective against. If your facility is unable to store the product, please contact C19therapeutics@msdh.ms.gov to discuss transfer to MSDH.**
  c. **MSDH will continue to distribute the limited supply of sotrovimab received on a weekly basis.**
- **On January 21, 2022, the FDA expanded the use of the antiviral remdesivir in the outpatient setting, to allow for treatment of adults and pediatric patients with mild to moderate disease who are at high risk of progression to severe COVID-19 (FDA Takes Actions to Expand Use of Treatment for Outpatients with Mild-to-Moderate COVID-19 | FDA).**
  a. **Remdesivir in the outpatient setting for these high-risk non-hospitalized patents is given via intravenous infusion for a total of three days.**
  b. **May be used in pediatric patients less than 12 years weighing at least 3.5 kg.**
  c. **Facilities may continue to order remdesivir as previous.**
  d. **See 2022-01-07-MLNC-SE | CMS for CMS outpatient remdesivir administration codes.**

COVID-19 Therapeutics

1. Consistent reporting of utilization of monoclonal antibodies and oral antiviral medications is very important. Reporting to HHS and MSDH impacts your distribution of our state's allocation of COVID-19 therapeutic products.
   a. Administration and on-hand inventory of sotrovimab should be reported **weekly** in HHS Protect/Teletracking.

   b. Administration, on-hand inventory, and product requests for sotrovimab should be entered **weekly (Tuesdays)** through the MSDH REDCap Survey.
   c. Administration and on-hand inventory of Evusheld, Paxlovid, and molnupiravir should be reported at the **end of every business day** in the Health Provider Order Portal (HPOP).
2. Product is in short supply, so the standing order for monoclonal antibodies is no longer in effect. Patients should be triaged and clinically evaluated by a provider or physician in order to receive monoclonal antibodies or oral antivirals for COVID-19.
3. For a provider to select the best treatment option for individuals who will receive the greatest benefit from therapy given supply constraints, the following should be considered:
   a. Your facility's availability of monoclonal antibodies, molnupiravir, Paxlovid and remdesivir. Because Mississippi's allocation is small, MSDH is distributing the very limited supply of monoclonal antibodies and oral antivirals to hospital Centers of Excellence and Federally Qualified Health Centers in the state at this time. Remdesivir is purchased commercially and is not distributed by MSDH.
   b. Feasibility of parenteral administration of monoclonal antibodies or remdesivir
   c. Drug-drug interactions (please review Paxlovid EUA)
   d. Renal and hepatic function (please review Paxlovid EUA & remdesivir insert)
   e. High risk indications in each individual (refer to tiered risk groups in graphic below).
   f. Clinical decision guide for COVID-19 treatment: Adult or pediatric (age 12 and older and weight 40kg or greater) with mild to moderate COVID-19 & high risk for progression to severe disease (phe.gov)
4. Prioritize treatment over post-exposure prophylaxis

Please use this resource as a guide for implementing COVID-19 therapeutics into your practice: https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/USG-COVID19-Tx-Playbook.pdf.

COVID-19 Treatment Guidelines When There Are Logistical or Supply Constraints

Tier	Risk Group
1	Immunocompromised individuals not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to their underlying conditions, regardless of vaccine status (see Immunocompromising Conditions below); *or* Unvaccinated individuals at the highest risk of severe disease (anyone aged ≥75 years or anyone aged ≥65 years with additional risk factors).
2	Unvaccinated individuals at risk of severe disease not included in Tier 1 (anyone aged ≥65 years or anyone aged <65 years with clinical risk factors)
3	Vaccinated individuals at high risk of severe disease (anyone aged ≥75 years or anyone aged ≥65 years with clinical risk factors) **Note:** Vaccinated individuals who have not received a COVID-19 vaccine booster dose are likely at higher risk for severe disease; patients in this situation within this tier should be prioritized for treatment.
4	Vaccinated individuals at risk of severe disease (anyone aged ≥65 years or anyone aged <65 with clinical risk factors) **Note:** Vaccinated individuals who have not received a COVID-19 vaccine booster dose are likely at higher risk for severe disease; patients in this situation within this tier should be prioritized for treatment.

https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-patient-prioritization-for-outpatient-therapies/

7

UNCLASSIFIED / FOR PUBLIC DISTRIBUTION

MISSISSIPPI STATE DEPARTMENT OF HEALTH

Vaccination

1. Continue to promote COVID-19 vaccination and boosters.
2. Clearly communicate when vaccinations are available in your facility and age group information respective to the different products.

Resources:
Sotrovimab: https://www.fda.gov/media/149534/download
Molnupiravir: https://www.merck.com/eua/molnupiravir-hcp-fact-sheet.pdf
Paxlovid: https://www.fda.gov/media/155050/download
Veklury (remdesivir): veklury_pi.pdf (gilead.com)

Please email C19Therapeutics@msdh.ms.gov with any questions or concerns.

Regards,

Paul Byers, MD
State Epidemiologist

MISSISSIPPI STATE DEPARTMENT OF HEALTH

Alerting Message Specification Settings

Originating Agency:	Mississippi State Department of Health
Alerting Program:	MS Health Alert Network (MS HAN)
Message Identifier:	MSHAN-20220126-00553-ALT
Program (HAN) Type:	Health Alert
Status (Type):	Actual ()
Message Type:	Alert
Reference:	MSHAN-00553
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)).