



MISSISSIPPI STATE DEPARTMENT OF HEALTH

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

MESSAGE ID: MSHAN-202100907-00535-ALT (Health Alert)
RECIPIENTS: All Physicians, Hospitals, ERs, ICPs, NPs, and
Healthcare Providers – Statewide
Tuesday, September 7, 2021
SUBJECT: Mississippi Statewide Standing Order for REGEN-COV,
Bamlanivimab and Etesevimab, and Sotrovimab

Administration of Monoclonal Antibodies for COVID-19

Updated Guidance:

- In addition to REGEN-COV and sotrovimab, bamlanivimab/etesevimab is now authorized for the early treatment of COVID-19.
- **Important:** all doses of REGEN-COV and bamlanivimab/etesevimab must be documented in HHS Protect to ensure future orders will be filled. To report weekly utilization to HHS, register your site by emailing hhs-protect@teletracking.com. Report weekly utilization to MSDH by emailing your contact information to monoclonals@msdh.ms.gov, and you will receive a link to the reporting survey.
- MSDH is strongly recommending the use of REGEN-COV for post-exposure prophylaxis as outlined in the current EUAs.

Purpose:

To reduce morbidity and mortality from SARS-CoV-2, the virus that causes COVID-19, by treating all persons who meet the treatment criteria established by the U.S. Food and Drug Administration (FDA) outlined in the Emergency Use Authorization (EUA) for the monoclonal antibody product.

Policy:

Under these standing orders, eligible healthcare providers are authorized to administer **REGEN-COV, bamlanivimab/etesevimab, or sotrovimab** to adults and adolescents 12 years of age and older weighing at least 40 kg with positive results of direct SARS-CoV-2 testing within 10 days of symptom onset who meet any of the criteria below.

- Older age (for example, age ≥ 65 years of age)
- Obesity or being overweight (for example, BMI >25 kg/m², or if age 12-17, have BMI $\geq 85^{\text{th}}$ percentile for their age and gender)
- 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, interstitial lung disease, cystic fibrosis, and pulmonary hypertension)

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- ix. Sickle cell disease
- x. Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)
- xi. Having a medical-related technological dependence [for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)]

Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19 and authorization of REGEN-COV under the EUA is not limited to the medical conditions or factors listed above.

Monoclonal antibodies are not authorized for use in patients:

- i. Who are hospitalized due to COVID-19, OR
- ii. Who require oxygen therapy due to COVID-19, OR
- iii. 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.

Post-Exposure Prophylaxis (REGEN-COV):

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, REGEN-COV (casirivimab and imdevimab) co-formulated product and REGEN-COV (casirivimab and imdevimab) supplied as individual vials to be administered together, 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 Centers for Disease Control and Prevention or
 - who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes, prisons)

The guidance in the EUA for the monoclonal antibodies can change frequently. Please refer to the references below for the latest guidance:

Regeneron Pharmaceuticals:

[treatment-covid19-eua-fact-sheet-for-hcp.pdf \(regeneron.com\)](https://www.regeneron.com/treatment-covid19-eua-fact-sheet-for-hcp.pdf)

Eli Lilly and Company:

[Fact Sheet For Health Care Providers Emergency Use Authorization \(Eua\) Of Bamlanivimab And Etesevimab 08272021 \(fda.gov\)](https://www.fda.gov/oc/2020/08/27/fact-sheet-for-health-care-providers-emergency-use-authorization-eua-of-bamlanivimab-and-etesevimab-08272021)

GlaxoSmithKline:

[SOTROVIMAB-EUA.PDF \(gskpro.com\)](https://www.gsk.com/~/media/documents/default/source/SOTROVIMAB-EUA.PDF)



FOR REGEN-COV:

Order to dispense:

The healthcare provider is authorized to dispense the below formulations of monoclonal antibodies:

REGEN-COV (600 mg casirivimab and 600 mg imdevimab) or (300 mg casirivimab and 300 mg imdevimab)

Formulations

- Single product vials:
 - Casirivimab 120 mg/mL - 5mL total (from 2.5 or 11.1 mL vials) for 600 mg casirivimab
 - Casirivimab 120 mg/mL – 2.5mL total (from 2.5 or 11.1 mL vials) for 300 mg casirivimab
 - Imdevimab 120 mg/mL - 5mL total (from 2.5 or 11.1 mL vials) for 600 mg imdevimab
 - Imdevimab 120 mg/mL – 2.5mL total (from 2.5 or 11.1 mL vials) for 300 mg imdevimab
- Co-formulated vials:
 - Casirivimab 60 mg/mL and imdevimab 60 mg/mL - 10mL total for 600 mg casirivimab and 600 mg imdevimab
 - Casirivimab 60 mg/mL and imdevimab 60 mg/mL - 5mL total for 300 mg casirivimab and 300 mg imdevimab

The patient must be provided a copy of the Patient Fact Sheet:

- English: [treatment-covid19-eua-fact-sheet-for-patient.pdf \(regeneron.com\)](https://www.regeneron.com/treatment-covid19-eua-fact-sheet-for-patient.pdf)
- Spanish: [treatment-covid19-eua-fact-sheet-patient-spanish.pdf \(regeneron.com\)](https://www.regeneron.com/treatment-covid19-eua-fact-sheet-patient-spanish.pdf)

Dosing:

TREATMENT:

The dosage in adult and pediatric patients (12 years of age and older weighing at least 40 kg) is **600 mg of casirivimab and 600 mg of imdevimab administered** together as a single intravenous infusion or by subcutaneous injection.

POST-EXPOSURE PROPHYLAXIS (PEP):

The dosage in adult and pediatric individuals (12 years of age and older weighing at least 40 kg) is **600 mg of casirivimab and 600 mg of imdevimab** administered by subcutaneous injection or together as a single intravenous infusion.

For individuals in whom repeat dosing is determined to be appropriate for ongoing exposure to SARS-CoV-2 for longer than 4 weeks and who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination, the initial dose is 600 mg of casirivimab and 600 mg of imdevimab by subcutaneous injection or intravenous infusion followed by subsequent **repeat dosing of 300 mg of casirivimab and 300 mg of imdevimab by subcutaneous injection or intravenous infusion once every 4 weeks for the duration of ongoing exposure.**



Preparation:

INTRAVENOUS INFUSION

Dilution Instructions for 600 mg Casirivimab and 600 mg Imdevimab for IV Infusion

Size of Prefilled 0.9% Sodium Chloride Infusion Bag	Preparing Using Co-Formulated Vial	Preparing Using Individual Vials
50 mL	Add 10 mL of co-formulated casirivimab and imdevimab (1 vial) into a prefilled 0.9% sodium chloride infusion bag and administer as instructed	Add : <ul style="list-style-type: none"> • 5 mL of casirivimab (may use 2 vials of 2.5 mL OR 5 mL from 1 vial of 11.1 mL) • 5 mL of imdevimab (may use 2 vials of 2.5 mL OR 5 mL from 1 vial of 11.1 mL) Inject into prefilled 0.9% sodium chloride infusion bag and administer as instructed below
100 mL		
150 mL		
250 mL		

Dilution Instructions for 300 mg Casirivimab and 300 mg Imdevimab for IV Infusion for Repeat Dosing for PEP

Size of Prefilled 0.9% Sodium Chloride Infusion Bag	Preparing Using Co-Formulated Vial	Preparing Using Individual Vials
50 mL	Add 5 mL of co-formulated casirivimab and imdevimab (0.5 vial) into a prefilled 0.9% sodium chloride infusion bag and administer as instructed	Add : <ul style="list-style-type: none"> • 2.5 mL of casirivimab (may use 1 vial of 2.5 mL OR 2.5 mL from 1 vial of 11.1 mL) • 2.5 mL of imdevimab (may use 1 vial of 2.5 mL OR 2.5 mL from 1 vial of 11.1 mL) Inject into prefilled 0.9% sodium chloride infusion bag and administer as instructed below
100 mL		
150 mL		
250 mL		



SUBCUTANEOUS INJECTION

Preparation Instructions for 600 mg Casirivimab and 600 mg Imdevimab for Subcutaneous Injection

Prepare 600 mg of Casirivimab and 600 mg of Imdevimab	Preparation of 4 syringes
Using Co-Formulated Vial	Withdraw 2.5 mL solution per syringe into FOUR separate syringes
Using Individual Vials	Casirivimab: Withdraw 2.5 mL solution per syringe into TWO separate syringes Imdevimab: Withdraw 2.5 mL solution per syringe into TWO separate syringes

Preparation Instructions for 300 mg Casirivimab and 600 mg Imdevimab for Subcutaneous Injection for Repeat Dosing for PEP

Prepare 300 mg of Casirivimab and 300 mg of Imdevimab	Preparation of 2 syringes
Using Co-Formulated Vial	Withdraw 2.5 mL solution per syringe into TWO separate syringes
Using Individual Vials	Casirivimab: Withdraw 2.5 mL solution per syringe into ONE syringe Imdevimab: Withdraw 2.5 mL solution per syringe into ONE syringe

Administration:

INTRAVENOUS INFUSION

Casirivimab and imdevimab infusion solution should be administered by a qualified healthcare professional using aseptic technique.

- Gather the recommended materials for infusion:
 - Polyvinyl chloride (PVC), polyethylene (PE)-lined PVC, or polyurethane (PU) infusion set
 - In-line or add-on 0.2-micron polyethersulfone (PES) filter
- Attach the infusion set to the intravenous bag
- Prime the infusion set
- Administer the entire infusion solution in the bag via pump or gravity through an intravenous line containing a sterile, in-line or add-on 0.2-micron polyethersulfone (PES) filter at the specified rate below

Administration Rate for 600 mg Casirivimab and 600 mg Imdevimab

Size of Prefilled 0.9% Sodium Chloride Infusion Bag Used	Maximum Infusion Rate	Minimum Infusion Time
50 mL	180 mL/hr	20 minutes
100 mL	310 mL/hr	21 minutes
150 mL	310 mL/hr	31 minutes
250 mL	310 mL/hr	50 minutes



Administration Rate for 300 mg Casirivimab and 300 mg Imdevimab for Repeat Dosing for PEP

Size of Prefilled 0.9% Sodium Chloride Infusion Bag Used	Maximum Infusion Rate	Minimum Infusion Time
50 mL	165 mL/hr	20 minutes
100 mL	310 mL/hr	20 minutes
150 mL	310 mL/hr	30 minutes
250 mL	310 mL/hr	49 minutes

- Due to potential overflow of prefilled saline bags, the entire infusion solution in the bag should be administered to avoid underdosage.
- The prepared infusion solution should not be administered simultaneously with any other medication. The compatibility of casirivimab and imdevimab injection with intravenous solutions and medications other than 0.9% Sodium Chloride Injection is not known.
- After infusion is complete, flush the tubing with 0.9% Sodium Chloride Injection to ensure delivery of the required dose.
- Discard unused product.

SUBCUTANEOUS INJECTION

- For the administration of 600 mg of casirivimab and 600 mg of imdevimab, gather 4 syringes and prepare for subcutaneous injections.
- For the administration of 300 mg of casirivimab and 300 mg of imdevimab for repeat PEP dosing, gather 2 syringes and prepare for subcutaneous injections.
- Administer the subcutaneous injections consecutively, each at a different injection site, into the thigh, back of the upper arm, or abdomen, except for 2 inches (5 cm) around the navel. The waistline should be avoided.
- When administering the subcutaneous injections, it is recommended that providers use different quadrants of the abdomen or upper thighs or back of the upper arms to space apart each 2.5 mL subcutaneous injection of casirivimab and imdevimab. DO NOT inject into skin that is tender, damaged, bruised, or scarred.

FOR BAMLANIVIMAB AND ETESEVIMAB

Order to dispense:

The healthcare provider is authorized to dispense the below formulations of monoclonal antibodies:
700 mg bamlanivimab and 1400 mg etesevimab

Formulations:

- Single product vials:
 - Bamlanivimab 700 mg/20 mL (35 mg/mL) per vial
 - One vial = 700 mg dose of bamlanivimab
 - Etesevimab 700 mg/20 mL (35 mg/mL) per vial
 - Two vials = 1400 mg dose of etesevimab

The patient must be provided a copy of the Patient Fact Sheet:

- English: bam-and-ete-eua-factsheet-patient.pdf (lilly.com)
- Spanish: bam-and-ete-eua-factsheet-patient-span.pdf (lilly.com)



Preparation:

INTRAVENOUS INFUSION ONLY

Bamlanivimab and etesevimab solution for infusion should be prepared by a qualified healthcare professional using aseptic technique:

- Gather the materials for preparation:
 - Polyvinyl chloride (PVC) or polyethylene (PE)-lined PVC, sterile prefilled infusion bag. Choose one of the following sizes:
 - Prefilled 50 mL, 100 mL, 150 mL, or 250 mL infusion bag containing 0.9% Sodium Chloride Injection
 - **One vial of bamlanivimab (700 mg/20 mL) and two vials of etesevimab (700 mg/20 mL).**
- Bamlanivimab and etesevimab are supplied in individual single-dose vials but are administered together using a single infusion bag.
- Remove 1 bamlanivimab vial and 2 etesevimab vials from refrigerated storage and allow to equilibrate to room temperature for approximately 20 minutes before preparation. Do not expose to direct heat. Do not shake the vials.
- Inspect both bamlanivimab and etesevimab vials visually for particulate matter and discoloration.
 - Bamlanivimab and etesevimab are clear to opalescent and colorless to slightly yellow to slightly brown solutions.
- Withdraw 20 mL from one bamlanivimab vial and 40 mL from two etesevimab vials and inject all 60 mL into a prefilled infusion bag containing 0.9% Sodium Chloride.
- Discard any product remaining in the vials.
- Gently invert the bag by hand approximately 10 times to mix. Do not shake.
- These products are preservative-free and therefore, the diluted infusion solution should be administered immediately.
- If immediate administration is not possible, store the diluted infusion solution for up to 24 hours at refrigerated temperature (2°C to 8°C [36°F to 46°F]) and up to 7 hours at room temperature (20°C to 25°C [68°F to 77°F]) including infusion time. If refrigerated, allow the infusion solution to equilibrate to room temperature for approximately 20 minutes prior to administration.

Administration:

INTRAVENOUS INFUSION ONLY

Bamlanivimab and etesevimab infusion solution should be administered by a qualified healthcare professional.

- Gather the materials for infusion:
 - Polyvinyl chloride (PVC) or polyethylene (PE)-lined PVC infusion set.
 - Use of an in-line or add-on 0.2/0.22 micron polyethersulfone (PES) filter is strongly recommended.
- Attach the infusion set to the IV bag.
- Prime the infusion set.
- Administer the entire infusion solution in the bag via pump or gravity according to the size of infusion bag used (see tables below).
- Due to potential overflow of prefilled saline bags, the entire infusion solution in the bag should be administered to avoid underdosage.



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- The prepared infusion solution should not be administered simultaneously with any other medication. The compatibility of bamlanivimab and etesevimab injection with IV solutions and medications other than 0.9% Sodium Chloride Injection is not known.
- Once infusion is complete, flush the tubing with 0.9% Sodium Chloride to ensure delivery of the required dose.
- Clinically monitor patients during administration and observe patients for at least 1 hour after infusion is complete.
- If the infusion must be discontinued due to an infusion reaction, discard any unused product.
- The use of closed system transfer devices (CSTDs), elastomeric pumps, and pneumatic transport with bamlanivimab has not been studied.

Recommended Administration Instructions for Bamlanivimab and Etesevimab for IV Infusion in Patients Weighing 50 kg or More:

Size of Prefilled 0.9% Sodium Chloride Infusion Bag	Maximum Infusion Rate	Minimum Infusion Time
50 mL	310 mL/hr	21 minutes
100 mL	310 mL/hr	31 minutes
150 mL	310 mL/hr	41 minutes
250 mL	310 mL/hr	60 minutes

Recommended Administration Instructions for Bamlanivimab and Etesevimab for IV Infusion in Patients Weighing 40kg-49kg:

Size of Prefilled 0.9% Sodium Chloride Infusion Bag	Maximum Infusion Rate	Minimum Infusion Time
50 mL	310 mL/hr	21 minutes
100 mL	310 mL/hr	31 minutes
150 mL	310 mL/hr	41 minutes
250 mL	266 mL/hr	70 minutes

FOR SOTROVIMAB:

Order to dispense:

The healthcare provider is authorized to dispense the below formulations of monoclonal antibodies:

500 mg sotrovimab:

Formulation:

- Single product vial: sotrovimab 500 mg/8 mL

The patient must be provided a copy of the Patient Fact Sheet:

- English: [SOTROVIMAB-PATIENT-FACT-SHEET.PDF \(gskpro.com\)](#)
- Spanish: [Sotrovimab Patient Fact Sheet \(Spanish\) - Emergency Use Authorization \(EUA\)](#)



Preparation:

INTRAVENOUS INFUSION ONLY

Sotrovimab is supplied in a single-dose vial and must be diluted prior to administration. Sotrovimab injection should be prepared by a qualified healthcare professional using aseptic technique.

- Gather the materials for preparation:
 - Polyvinyl chloride (PVC) or polyolefin (PO), sterile, prefilled infusion bag. Choose one of the following sizes: prefilled 50-mL or 100-mL infusion bag containing 0.9% Sodium Chloride Injection, and
 - One vial of sotrovimab (500 mg/8 mL).
- Remove one vial of sotrovimab from refrigerated storage and allow to equilibrate to room temperature, protected from light, for approximately 15 minutes.
- Inspect the vial of sotrovimab visually for particulate matter and discoloration prior to administration. Should either be observed, the solution must be discarded and a fresh solution prepared. Sotrovimab is a clear, colorless or yellow to brown solution.
- Gently swirl the vial several times before use without creating air bubbles. Do not shake the vial.
- Withdraw 8 mL of sotrovimab from one vial and inject into the prefilled infusion bag containing 0.9% Sodium Chloride Injection.
- Discard any product remaining in the vial.
- Prior to the infusion, gently rock the infusion bag back and forth by hand 3 to 5 times. Do not invert the infusion bag. Avoid forming air bubbles.
- This product is preservative-free; therefore, the diluted infusion solution should be administered immediately. If immediate administration is not possible, store the diluted solution of sotrovimab up to 4 hours at room temperature (20°C to 25°C [68°F to 77°F]) or refrigerated up to 24 hours (2°C to 8°C [36°F to 46°F]).

Administration:

INTRAVENOUS INFUSION ONLY

Sotrovimab infusion solution should be administered by a qualified healthcare professional.

- Gather the materials for infusion:
 - Polyvinyl chloride (PVC) or polyolefin (PO) infusion set, and
 - Use of a 0.2 micron polyethersulfone (PES) filter is strongly recommended.
- Attach the infusion set to the IV bag using standard bore tubing.
- Prime the infusion set.
- Administer the entire infusion solution in the bag over 30 minutes. Due to potential overfill of prefilled saline bags, the entire infusion solution in the bag should be administered to avoid underdosage.
- Do not administer as an IV push or bolus.
- The prepared infusion solution should not be administered simultaneously with any other medication. The compatibility of sotrovimab with IV solutions and medications other than 0.9% Sodium Chloride Injection is not known.
- Once infusion is complete, flush the tubing with 0.9% Sodium Chloride to ensure delivery of the required dose.
- If the infusion must be discontinued due to an infusion reaction, discard unused product.



FOR REGEN-COV, BAMLANIVIMAB AND ETESEVIMAB, AND SOTROVIMAB:

Monitoring:

- Patients must be clinically monitored during administration of the medication AND observed for at least one-hour post-treatment to assess for potential adverse reactions.
- Proper treatments must be maintained on site for the management of rare anaphylactic reactions and the site must have the ability to activate EMS when needed.

Reporting and Recordkeeping:

- Healthcare providers must submit a report on all medication errors and ALL SERIOUS ADVERSE EVENTS potentially related to REGEN-COV, bamlanivimab and etesevimab. or sotrovimab. See EUA for instructions on reporting adverse events.
- A copy of the standing order signed by the Mississippi State Health Officer must be maintained on file and readily retrievable at each participating site.

Statement of Approval by the State Health Officer

The statewide standing order for monoclonal antibodies has been approved for use by authorized healthcare professionals as of Monday, September 7, 2021.

A handwritten signature in blue ink, appearing to read "Thomas Dobbs".

Thomas Dobbs, MD, MPH
State Health Officer



Alerting Message Specification Settings

Originating Agency: Mississippi State Department of Health
Alerting Program: MS Health Alert Network (MS HAN)
Message Identifier: MSHAN-20210907-00535-ALT
Program (HAN) Type: Health Alert
Status (Type): Actual ()
Message Type: Alert
Reference: MSHAN-00535
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)).