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 REGEN-COV monoclonal antibody product.

Policy:

Under these standing orders, eligible healthcare providers are authorized to administer REGEN-COV 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.

i. Older age (for example, age ≥65 years of age)
ii. Obesity or being overweight (for example, BMI >25 kg/m², or if age 12-17, have BMI ≥85th percentile for their age and gender)
iii. Pregnancy
iv. Chronic kidney disease
v. Diabetes
vi. Immunosuppressive disease or immunosuppressive treatment
vii. Cardiovascular disease (including congenital heart disease) or hypertension
viii. Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma, interstitial lung disease, cystic fibrosis, and pulmonary hypertension)
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))

xii. **Other medical conditions or factors (such as race and ethnicity) that may place individuals at an increased risk for progression to more severe disease.** Authorization of REGEN-COV under the current 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.

The guidance in the EUA for the monoclonal antibodies can change frequently. Please refer to the reference below for the latest guidance.
Regeneron Pharmaceuticals: treatment-covid19-eua-fact-sheet-for-hcp.pdf (regeneron.com)

Order to dispense:

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

REGEN-COV (casirivimab and imdevimab)

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

The patient must be provided a copy of the Patient Fact Sheet:
- English: treatment-covid19-eua-fact-sheet-for-patient.pdf (regeneron.com)

Preparation:

**INTRAVENOUS INFUSION**

<table>
<thead>
<tr>
<th>Size of Prefilled 0.9% Sodium Chloride Infusion Bag</th>
<th>Preparing 600 mg of Casirivimab and 600 mg of Imdevimab Using Co-Formulated Vial</th>
<th>Preparing 600 mg of Casirivimab and 600 mg of Imdevimab Using Individual Vials</th>
</tr>
</thead>
</table>
| 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:
  - 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) |
| 100 mL                                            |                                                                                 |                                                                                 |
| 150 mL                                            |                                                                                 |                                                                                 |
### SUBCUTANEOUS INJECTION

<table>
<thead>
<tr>
<th>Prepare 600 mg of Casirivimab and 600 mg of Imdevimab</th>
<th>Preparation of 4 syringes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Using Co-Formulated Vial</td>
<td>Withdraw 2.5 mL solution per syringe into FOUR separate syringes</td>
</tr>
<tr>
<td>Using Individual Vials</td>
<td>Casirivimab: Withdraw 2.5 mL solution per syringe into TWO separate syringes Imdevimab: Withdraw 2.5 mL solution per syringe into TWO separate syringes</td>
</tr>
</tbody>
</table>

**Administration:**

**INTRAVENOUS INFUSION**

- For the administration of 600 mg of casirivimab and 600 mg of imdevimab, gather the recommended materials for infusion:
- Polyvinyl chloride (PVC), polyethylene (PE)-lined PVC, or polyurethane (PU) infusion set, inline 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

<table>
<thead>
<tr>
<th>Size of Prefilled 0.9% Sodium Chloride Infusion Bag Used</th>
<th>Maximum Infusion Rate</th>
<th>Minimum Infusion Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 mL</td>
<td>180 mL/hr</td>
<td>20 minutes</td>
</tr>
<tr>
<td>100 mL</td>
<td>310 mL/hr</td>
<td>21 minutes</td>
</tr>
<tr>
<td>150 mL</td>
<td>310 mL/hr</td>
<td>31 minutes</td>
</tr>
<tr>
<td>250 mL</td>
<td>310 mL/hr</td>
<td>50 minutes</td>
</tr>
</tbody>
</table>

- Due to potential overfill 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.
• 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.

**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. 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 from August 16, 2021 to October 1, 2021.

_______ ______________________
Thomas Dobbs, MD, MPH
State Health Officer
Mississippi State Department of Health

_______ August 15, 2021___________
Date
Alerting Message Specification Settings

**Originating Agency:** Mississippi State Department of Health

**Alerting Program:** MS Health Alert Network (MS HAN)

**Message Identifier:** MSHAN-20210815-00529-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)).