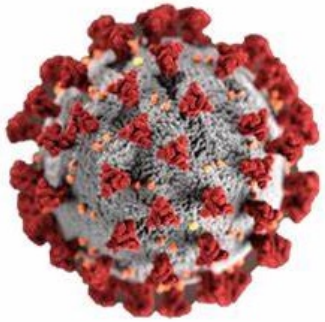
Learning Objectives

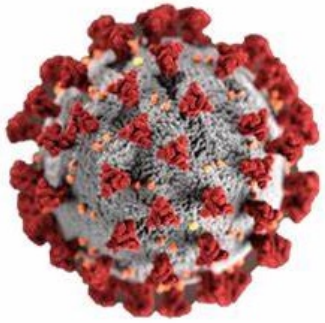
- Describe REGEN-COV (casirivimab and imdevimab)
- Identify purpose and indications for treatment
- Identify those for whom infusion is recommended.
- Understand adverse reaction(s) and how to respond.
- Describe how to safely infuse REGEN-COV (casirivimab and imdevimab)

About REGEN-COV and COVID-19

- COVID-19 is the disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
- REGEN-COV is a combination of casirivimab and imdevimab administered together for treatment of mild to moderate COVID-19 in patients with positive SARS-COV-2 viral test, and who are at high risk for progressing to severe COVID-19 and/or hospitalization and/or death
- Casirivimab and imdevimab are both monoclonal antibodies



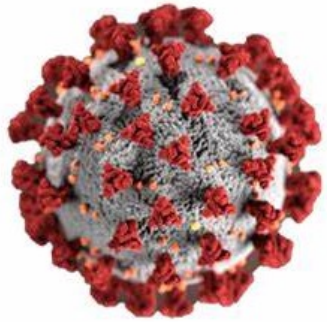
REGEN-COV (casirivimab and imdevimab) Mechanism of Action



- Monoclonal antibodies are proteins made in a laboratory that can fight off harmful pathogens such as viruses
- Casirivimab and imdevimab are two recombinant human monoclonal antibodies (mAbs) which bind to the spike protein receptor of the SARS-CoV-2 to block binding to the human ACE2 receptor
- Blocking the spike protein of the coronavirus can reduce viral replication

Emergency Use Authorization

- The FDA has issued Emergency Use Authorization for REGEN-COV (casirivimab and imdevimab)
- **Emergency Use Authorization** (EUA) authority allows the FDA to help strengthen the nation's public health protections against Chemical, Biological, Radiological, and Nuclear (CBRN) threats by facilitating the availability and use of medical countermeasures (MCMs) needed during public health emergencies.



REGEN-COV (casirivimab and imdevimab) Indications

Outpatient setting to treat mild to moderate COVID-19 in adults with high risk for progressing to severe COVID-19 and/or hospitalization.

High risk is defined as patients who meet at least one of the following criteria:

- BMI greater than 25
- Chronic kidney disease
- Pregnancy
- Diabetes
- Immunosuppressive disease
- Currently receiving immunosuppressive treatment
- 65 years or older
- Cardiovascular disease (including congenital heart disease)
- Hypertension

High Risk Indications (continued):

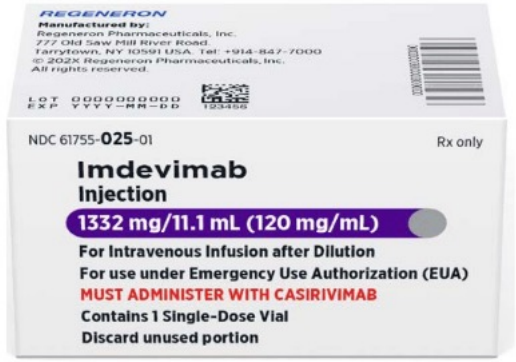
- Chronic Obstructive Pulmonary Disease/other chronic respiratory disease (asthma [moderate-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension
- Sickle cell disease
- Neurodevelopmental disorders (Cerebral palsy) or other conditions that confer medical complexity (genetic or metabolic syndromes and severe congenital anomalies)
- Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID 19)

Who should **not** receive REGEN-COV (casirivimab and imdevimab)?

- Patients hospitalized due to COVID-19*
- Patients requiring supplemental oxygen due to COVID-19
- Patients requiring increase in baseline supplemental oxygen due to COVID-19 in patients on chronic oxygen therapy due to an underlying condition that is non-COVID-19 related.

*Monoclonal antibodies may be associated with worse clinical outcomes when given to hospitalized COVID-19 patients requiring oxygen or mechanical ventilation.

REGEN-COV is a combination of Casirivimab and Imdevimab



Dosage of REGEN-COV (casirivimab and imdevimab)

- REGEN-COV must be diluted in the pharmacy with normal saline prior to administration.
- Dosage is:
  - Casirivimab 600 mg

    plus
  - Imdevimab 600 mg
- Administered together as single 100 mL infusion

Administration

- There should be immediate access to medication and equipment to treat severe infusion reaction/anaphylaxis.
- REGEN-COV (casirivimab and imdevimab) is administered as a single IV infusion **as soon as possible after positive viral test**.
- REGEN-COV is to be administered within 10 days of symptom onset; use later in disease may lead to worse outcomes
- REGEN-COV is available as two separate vials **or** in a co-formulated single vial
- REGEN-COV is administered as a single 100 mL infusion diluted in normal saline
- REGEN-COV is administered over 21 minutes (and up to 50 minutes if needed)

Infusion Instructions

- Gather recommended materials
  - PVC, Polyethylene (PE) –lined PVC, or Polyurethane infusion set
  - In-line or add-on 0.2 micron polyethersulfone (PES) filter
- Attach infusion set to IV bag containing REGEN-COV (casirivimab and imdevimab) and prime IV line
- Administer as IV infusion via infusion pump over at least 21 minutes via IV line containing sterile, in-line, or add-on 0.2 micron PES filter
- Do not administer REGEN-COV (casirivimab and imdevimab) simultaneously with any other medication.
- After infusion is complete, **flush <u>IV tubing</u>** with Normal Saline

Patient Monitoring During and After the Infusion

- Patients are to be **monitored during the infusion and for at least one hour after the infusion is complete**.
- Staff are to wear appropriate PPE (Airborne Precautions) while caring for patients receiving REGEN-COV (casirivimab and imdevimab).
- Monitoring during and after infusion is to include
  - Vital signs
  - Signs and/or symptoms of infusion-related reactions

Infusion-related reactions

- Infusion-related reactions to REGEN-COV (casirivimab and imdevimab) are rare and can include:
  - Fever
  - Chills
  - Nausea
  - Headache
  - Bronchospasm
  - Hypotension
  - Angioedema
  - Throat irrigation
  - Rash, including urticaria, and/or pruritus
  - Myalgia
  - Dizziness

Anaphylaxis and Response

- There is potential for serious hypersensitivity reactions, including anaphylaxis.
- If signs and/or symptoms of clinically significant hypersensitivity reaction or anaphylaxis occur,
  - Immediately discontinue administration
  - Initiate appropriate medications and/or supportive care

Anaphylaxis and Response

Mandatory Requirements under the EUA:

- Use casirivimab & imdevimab only in authorized patient populations described in Fact Sheet
- Communicate to patients or parents/caregivers information consistent with the “Fact Sheet for Patients, Parents and Caregivers” prior to patient receiving casirivimab & imdevimab.
- Healthcare providers (to the extent practicable given the circumstances of the emergency) must document in the patient’s medical record that the patient/caregiver has been:
  - Given the “Fact Sheet for Patients, Parents and Caregivers”
  - Informed of alternatives to receiving authorized casirivimab & imdevimab
  - Informed that casirivimab & imdevimab are unapproved drugs authorized for use under this EUA.
- Patients with known hypersensitivity to any ingredient of casirivimab & imdevimab must not receive casirivimab & imdevimab. The prescriber is responsible for mandatory reporting of all drug errors and SAEs potentially related to casirivimab/imdevimab treatment within 7 calendar days from onset of event.

Documentation of Infusion

- The administering nurse should document the infusion times in the MAR on the day of infusion.
- The administering nurse should document in the patient chart the infusion times and include information detailing how the patient tolerated the infusion.

REGEN-COV (casirivimab and imdevimab)
Highlights

- Diluted into 100 mL of total volume with normal saline
- Infuse over 21 minutes (up to 50 minutes if needed)
- Use in-line or add-on 0.2 micron polyethersulfone (PES) filter for infusing
- Observe patients for one hour after the infusion
- Monitor vital signs and for infusion-related reactions during and after infusion
- Document infusion times in patient’s MAR on day of infusion