REGEN-COV Monoclonal Antibody Treatment Summary

(Document Owner: Nick Kashey, updated 12/9/2021)

Bottom Line: Legacy is now offering monoclonal antibody treatment for outpatients with mild to moderate COVID symptoms in the first 10 days of illness. See below for eligibility and process details.

What is REGEN-COV?

REGEN-COV (casirivimab/imdevimab) is a monoclonal antibody that has recently been authorized under emergency use rules as a subcutaneous injection for treatment of COVID positive patients at high risk for progression (see list below).

Who is eligible for treatment? Patients must be:

- Over age of 12 and weigh at least 88Lbs (40Kg)
- Be within 10 days of symptom onset
- Have mild to moderate symptoms of confirmed COVID (home test OK) and any **one** of the risk factors listed below. This list is not fully restrictive, other factors that add risk for progression to severe disease such as race or ethnicity may also be considered.
    - Older age (≥65 years)
    - Obesity or being overweight (BMI >25 kg/m2 or if age 12-17 with BMI ≥85th percentile for age and gender)
    - Pregnancy
    - Chronic kidney disease
    - Diabetes
    - Immunosuppressive disease or immunosuppressive treatment.
    - Cardiovascular disease (including congenital heart disease) or hypertension
    - Chronic lung diseases (e.g., COPD, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis, and pulmonary hypertension)
    - Sickle cell disease
    - Neurodevelopmental disorders (e.g., cerebral palsy) or other conditions that confer medical complexity (e.g., 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))

Of note, Regen-Cov is also approved for patients with risk factors with a high-risk exposure, but currently, Legacy is only treating patients with known COVID. We will reassess this once demand and capacity are more clearly established.

Who should not get REGEN-COV?

- Any patients that have had a severe allergic reaction to REGEN-COV in the past should not receive it.
- It is not authorized for patients who are hospitalized for COVID-19.
- Not authorized for patients requiring new O2 therapy for COVID-19, or patients who have an increased O2 requirement from baseline if already on O2 for other reasons.
- Patients who have been exhibiting COVID-19 symptoms for greater than 10 days.

How is REGEN-COV given?

- This is given in four subcutaneous 2.5mL injections during the same visit. (back of arms, belly, or upper thigh)
- Please remind patients to wear a T-shirt for easy access

What reactions are possible?

- Serious hypersensitivity reactions, including anaphylaxis, have been observed with REGEN-COV. This was generally observed within 1 hour of administration, though it was also seen more than 24 hours after infusion administration. These events appear to be rare (<1%, with only cases of anaphylaxis reported).
- REGEN-COV administration may result in clinical worsening of COVID-19, including need for hospitalization. It is unknown if the events observed in the patients were due to REGEN-COV or due to natural progression of disease.

- Most reactions were injection site reactions (erythema, pruritis, ecchymosis).

How effective is treatment?

- Data published in the EUA Fact sheet demonstrated an absolute risk reduction of COVID-19 related hospitalization or all cause death of 2.2% (3.2% in placebo group, 1.0% in treatment group, N =1,484). This is a 70% relative risk reduction in these events and calculates to a number needed to treat of 46 patients to prevent 1 event of COVID-19 related hospitalization or all cause death.

Where can my patient receive REGEN-COV?

- Legacy has an administration site on the System Office campus at the 1120 building and at Salmon Creek. Patients will be administered the medication in a tent in the parking lot and will be asked to remain in their vehicle for the hour-long observation period.

How do I order REGEN-COV?

On Legacy Epic (see Epic tipsheet for screenshots)

- Use the SmartSet titled "***COVID-19 Monoclonal Antibody Treatment"***
- This SmartSet includes:
    1. Referral orders for scheduling the patient for administration.
    2. The medication order & prn emergency meds.
    3. Necessary documentation of consent
    4. Patient instructions with links to the medication information (EUA)
- The referral order will be managed by the scheduling staff at the 1120 Drive through testing site, they will reach out to your patient and schedule a time to come get the treatment.
- You need to document patient consent in your chart note with this SmartText: AMB COVID-19 MONOCLONAL ANTIBODY CONSENT
- You should add links to the EUA to the Patient Instructions with this SmartText: AMB COVID-19 MONCLONAL ANTIBODY PT INSTRUCTIONS
- If you are ordering this treatment through a Telephone Encounter which does not have an AVS, use the SmartText above to send a MyHealth message to the patient with the EUA link.

Not on Legacy Epic

- The process is similar to our PCR testing referral process, it is the same team handling the scheduling of patients, and goes as follows:
    - Ensure the patient meets criteria (details on attached order form)
    - Fill out the paper order form
    - Fax form and a facesheet to: 503-415-5139
    - The Legacy team will call the patient and schedule them for treatment at either of our 2 sites

What do I need to discuss with my patient?

- Patients who qualify for REGEN-COV should receive the information provided in the REGEN-COV Patient FAQ (EUA authorization). They should be informed of potential risks as well as treatment alternatives and that the medications in REGEN-COV are unapproved and are authorized for use under an Emergency Use Authorization (EUA). Please document with AMB COVID-19 MONOCLONAL ANTIBODY CONSENT.
- The centralized scheduling team from 1120 will be calling them to schedule the appointment in NW Portland
- They will be getting 4 injections at once
- They will need to sit in their car for 1 hour to be observed.
- They should wear a T-shirt or something that makes their upper arm and abdomen accessible.