Regen-Cov Emergency Use Authorization (EUA) Checklist

Criteria for Use:

This EUA is for the use of the product Regen-Cov for the prophylaxis and treatment of mild to moderate COVID19 in adults and pediatric patients with exposure and/or positive results SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

☐ Regen-Cov should be administered as soon as possible after exposure and/or positive viral test for SARS-CoV2 and within 10 days of exposure, asymptomatic positive test and/or symptom onset.

Patient has **at least one** of the following High Risk criteria (check all that apply):

☐ Body mass index (BMI) >25
☐ Age ≥65 years
☐ Chronic kidney disease
☐ Diabetes
☐ Immunosuppressive disease or currently
☐receiving immunosuppressive treatment
☐ Cardiovascular Disease/HTN
☐ Chronic respiratory disease
☐ Pregnancy
☐ Neurodevelopmental disorder
☐ Sickle Cell Disease

☐ Are 12 – 17 years of age AND >40kg
- o BMI ≥85th percentile for their age and gender based on CDC growth charts, CDC growth charts,
- o One of the above criteria
- o Medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR chronic respiratory disease that requires daily medication for control.

☐ For post exposure prophylaxsis:

☐ Patient must have a direct exposure **AND** at least one of the High Risk Criteria listed above **AND**
☐ Not be fully vaccinated **OR**
☐ Not expected to mount an immune response due to immunosuppressive disease or treatment **OR**
☐ Live in a close contact facility (ex. Nursing home, prison, group home, etc…)

☐ **EXCLUSION Criteria *NOT* met.**

Regen-Cov is *not* authorized for patients:

- o hospitalized due to COVID-19, OR
- o require oxygen therapy due to COVID-19, OR
- o 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.
- o with known hypersensitivity to any ingredient of Regeneron.

Patient Communication:

As the healthcare provider, you must communicate to your patient or parent/caregiver, as age appropriate, information consistent with the "Fact Sheet for Patients, Parents and Caregivers" (and provide a copy of the Fact Sheet) prior to the patient receiving Regeneron. Regeneron HCP link Links to fact sheets are also available on the IV guideline.

- **Provide** Fact Sheet: Regeneron P/C link (English) Regeneron P/C link (Spanish)

- **Communicate:** The FDA has authorized the emergency use of Regeneron for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV2 viral testing and who are at high risk for progressing to severe COVID-19 and/or hospitalization. Regeneron is an unapproved drug that is authorized for use under this Emergency Use Authorization.

- **Communicate:** The significant known and potential risks and benefits of Regeneron, and the extent to which such potential risks and benefits are unknown.

- **Communicate:** Information on available alternative treatments and the risks and benefits of those alternatives, including clinical trials.

  Sotrovimab is an alternative antibody infusion for patients who have mild to moderate COVID-19 who are at high risk for progressing to severe COVID-19 and/or hospitalization. Additional information on COVID-19 treatments can be found at https://www.cdc.gov/coronavirus/2019-ncov/index.html.

- The patient or parent/caregiver has the option to accept or refuse Regeneron. Patient or caregiver **agrees to receive Regeneron.**

- **Communicate:** Patients treated with Regeneron should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect "high touch" surfaces, and frequent handwashing) according to CDC guidelines.

- **Document** in the patient's medical record that the patient/caregiver has been:

  a. Given the "Fact Sheet for Patients, Parents and Caregivers",
  b. Informed of alternatives to receiving authorized Regeneron, and
  c. Informed that Regeneron is an unapproved drug that is authorized for use under this Emergency Use Authorization.