



DEPARTMENT OF
HEALTH AND HUMAN SERVICES

Promoting and protecting health, well-being, self-sufficiency, and safety of all in Marin County.

September 2, 2021



Benita McLarin, FACHE
DIRECTOR

Matthew Willis, MD, MPH
PUBLIC HEALTH OFFICER

Lisa M. Santora, MD, MPH
DEPUTY PUBLIC HEALTH OFFICER

3240 Kerner Boulevard
San Rafael, CA 94901
415 473 4163 T
415 473 2326 F
415 473 3232 TTY
marinhhs.org/public-health

PUBLIC HEALTH ADVISORY

Re: Monoclonal Antibody Therapy

Marin County Public Health is recommending that healthcare providers gain the capacity to administer monoclonal antibody therapy for their patients when indicated.

This advisory provides information about Regen-Cov (casirivimab and imdevimab), manufactured by Regeneron Pharmaceuticals. The FDA has recently expanded the Emergency Use Authorization to include subcutaneous route of administration, making this product more feasible to administer in routine healthcare settings. This product is available to healthcare providers at no cost.

For non-hospitalized patients with certain risk factors for disease progression, the use of anti-SARS-CoV-2 monoclonal antibody products reduces the risk of hospitalization and death.

Indications for the use of Regen-Cov:

Regen-Cov is authorized for the treatment of mild to moderate coronavirus disease (COVID-19) in adult and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

Regen-Cov is also authorized for post-exposure prophylaxis in certain settings of known SARS-CoV-2 exposures for individuals who are at high risk for progression to severe COVID-19.

High risk conditions that make an individual a candidate for receiving Regen-Cov:

- Older age (age \geq 65 years of age)
- Obesity or being overweight (BMI $>$ 25 kg/m², or if age 12-17, have BMI \geq 85th 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 (chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension)
- Sickle cell disease
- Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, 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))
 - Clinical discretion should be applied on a case by case basis, and patients outside of these groups may benefit from treatment.

Routes of Administration:

Regen-Co may be administered by intravenous infusion or subcutaneous injection.

Time limits for Regen-Cov treatment:

Treatment

- Administer as soon as possible after positive SARS-CoV-2 viral testing and within 10 days of symptom onset

Post-exposure Prophylaxis

- Treat as soon as possible following exposure to SARS-CoV-2 in settings of increased risk.

Medical Supervision:

- Administer casirivimab and imdevimab using the co-formulated solution in a vial or using the individual vials.
- Clinically monitor patients after injections and observe patients for at least 1 hour after injections.
- For both treatment and post-exposure prophylaxis, subcutaneous injection is an alternative route of administration when intravenous administration is not feasible and would lead to delay in treatment.

Regen-Cov may only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion or hypersensitivity reactions, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.

Health care providers must submit a report on all medication errors and all serious adverse events potentially related to Regen-Cov.

- Patients treated with Regen-Cov 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.

Contraindications:

Regen-Cov is contraindicated in individuals with previous severe hypersensitivity reactions, including anaphylaxis, to Regen-Cov.

Limitations of Authorized Use:

- Regen-Cov is not authorized for use in patients:
- o who are hospitalized due to COVID-19, OR
 - o who require oxygen therapy due to COVID-19

Preparation for Subcutaneous Injection:

Remove the casirivimab and imdevimab vial(s) from refrigerated storage and allow to equilibrate to room temperature for approximately 20 minutes before preparation. Do not shake the vials. The solution for each vial should be clear to slightly opalescent, colorless to pale yellow.

1. Casirivimab and imdevimab should be prepared using four syringes
2. Withdraw the appropriate amount of solution into each syringe. Prepare all syringes at the same time.
3. Replace the 21-gauge transfer needle with a 25-gauge or 27-gauge needle for subcutaneous injection.
4. This product is preservative-free and therefore, the prepared syringes should be administered immediately. If immediate administration is not possible, store the prepared casirivimab and imdevimab syringes in the refrigerator for no more than 4 hours or at room temperature up to 25°C (77°F) for no more than 4 total hours. If refrigerated, allow the syringes to equilibrate to room temperature for approximately 20 minutes prior to administration.

Signs and symptoms of infusion-related reactions:

Fever, difficulty breathing, reduced oxygen saturation, chills, fatigue, arrhythmia (e.g., atrial fibrillation, tachycardia, bradycardia), chest pain or discomfort, weakness, altered mental status, nausea, headache, bronchospasm, hypotension, hypertension, angioedema, throat irritation, rash

including urticaria, pruritus, myalgia, vasovagal reactions (e.g., pre-syncope, syncope), dizziness, and diaphoresis.

Local experience has been that other than mild local reactions at the injection sites, reactions have been mild.

Obtaining Regen-Cov:

Providers can order this product directly from the manufacturer here: [Direct Ordering of Monoclonal Antibodies](#)

Alternatively, supplies can be obtained through the Marin County Medical Operational Area Coordinator, at MHOAC@marincounty.org

References:

FDA statement regarding post exposure prophylaxis:
<https://www.fda.gov/drugs/drug-safety-and-availability/fda-authorizes-regen-cov-monoclonal-antibody-therapy-post-exposure-prophylaxis-prevention-covid-19>

FDA Regen-Cov fact sheet:
<https://www.fda.gov/media/145611/download>

NIH summary of evidence and clinical trials:
<https://www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-antibody-products/anti-sars-cov-2-monoclonal-antibodies/>

Results of clinical trial of subcutaneous Regen-Cov:
<https://www.nejm.org/doi/full/10.1056/NEJMoa2109682>