

**9/12/2021**

**UNDER NO CIRCUMSTANCES SHOULD ONE CALL THE HATZALAH EMERGENCY DISPATCH LINE REGARDING THIS THERAPY**

### **What is Monoclonal Antibody Therapy?**

Monoclonal antibodies are laboratory-made proteins that mimic the immune system's ability to fight off harmful antigens such as viruses. Regen-cov is a monoclonal antibody cocktail composed of two slightly different antibodies that target the spike protein on the SARS-COV2 virus, preventing it from binding to the receptors in our body that allows it to replicate, and cause damage. The two antibodies in the Regen-cov cocktail are called casirivimab and imdevimab

### **What is Regen-cov?**

Regen-cov is an investigational medicine used for the treatment of COVID-19 in non-hospitalized adults and adolescents 12 years of age and older with mild to moderate symptoms who weigh 88 pounds (40 kg) or more, and who are at high risk for developing severe COVID-19 symptoms or the need for hospitalization. Regen-cov is investigational because it is still being studied. However, there have been a number of studies at this point showing the benefit of Regen-cov in preventing progression and worsening of COVID-19 symptoms.

The FDA has authorized the emergency use of Regen-cov for the treatment of COVID-19 under an Emergency Use Authorization (EUA). For more information on EUA, see the section "What is an Emergency Use Authorization (EUA)?" at the end of this Fact Sheet.

### **Who is eligible for this treatment?**

- People who are high risk who have tested positive for COVID
- People who are high risk who do not have COVID, but were exposed to someone with COVID. This is known as post exposure prophylaxis.
- You must be considered "high risk" by the EUA. See list here

### **List of high risk conditions**

The following is the list of high risk conditions that qualify one to receive Regen-cov either as treatment for COVID or for post exposure prophylaxis.

The following medical conditions or other factors may place adults and pediatric patients (age 12-17 years and weighing at least 40 kg) at higher risk for progression to severe COVID-19:

- Older age (for example, age  $\geq 65$  years of age)
- Obesity or being overweight (for example, BMI  $> 25$  kg/m<sup>2</sup>, or if age 12-17, have BMI  $\geq 85$ th percentile for their age and gender based on CDC growth charts, [https://www.cdc.gov/growthcharts/clinical\\_charts.htm](https://www.cdc.gov/growthcharts/clinical_charts.htm))
- Pregnancy
- Chronic kidney disease
- Diabetes

- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung diseases (for example, 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))

Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19 and authorization of REGEN-COV under the EUA is not limited to the medical conditions or factors listed above. For additional information on medical conditions and factors associated with increased risk for progression to severe COVID, see the CDC website:

<https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>. Healthcare providers should consider the benefit-risk for an individual patient.

### **How is the medication given?**

If you are receiving Regen-cov because you have COVID, it will be given as an intravenous infusion that takes 20 minutes, followed by a 60 minute observation period. Although we have very talented nurses who are experts at IVs, every now and then we have a patient who we can't get an IV on. In these rare cases, we can give it as a series of 4 shots, followed by the 60 minute observation period.

If you are receiving Regen-cov for post exposure prophylaxis, it can be given as an IV infusion or as a series of 4 injections.

### **Is there a maximum time frame for one to receive this therapy?**

The EUA only allows this therapy to be given within 10 days of symptom onset. However, the therapy is most effective in the first couple of days after becoming positive. Therefore, it is important to receive the treatment as soon as possible after becoming positive, or after being exposed to someone with COVID.

### **How do I sign up to receive Regen-cov?**

If you tested positive you need a physician referral to receive the therapy. Many of the local doctors have referred patients to us already, and are familiar with how to access our physician referral form. If your doctor is not familiar with our referral process, have them contact us at 410-585-0054, extension 2, or email us at [covidtherapy@hatzalahbaltimore.org](mailto:covidtherapy@hatzalahbaltimore.org) and we will give them access to our physician referral site.

If you would like to sign up to receive it as post exposure prophylaxis, you sign up by yourself through our post exposure self referral form on the Hatzalah Website.

**What do I do if I don't have a regular doctor, I can't get in touch with my regular doctor, or my doctor is not familiar with the therapy, and will not refer me?**

In these cases, we have doctors on our staff who can screen you and if you are eligible will fill out a referral form for you. If you need this service, please call us at 410-585-0054, extension 2. Of course if you do have a doctor who will fill out a referral, we ask that you go through your doctor for the referral, since your doctor knows you the best.

**Can this therapy be obtained at any Dr office or Hospital?**

No, only authorized providers can provide this therapy.

**Is there an out of pocket expense for this therapy?**

No, this therapy is covered by the US Governments, Department of Health and Human Services, and is covered by all insurances. If you do not have insurance, you do not need to pay out of pocket for this, it will be paid for by the government.

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**Can I eat and drink during the infusion?**

We ask that people receiving the infusion not eat or drink, and keep their mask on at all times, for the safety of the staff.

**What should I tell my healthcare provider before I receive Regen-cov?**

Tell your healthcare provider about all of your medical conditions, including if you:

Have any allergies

Are pregnant or plan to become pregnant

Are breastfeeding or plan to breastfeed

Have any serious illnesses

Are taking any medications (prescription, over-the-counter, vitamins, and herbal products)

**What is an Emergency Use Authorization (EUA)?**

The United States FDA has made Regen-cov available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic. Regen-cov has not undergone the same type of review as an FDA-approved or cleared product. The FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the product meets certain criteria for safety, performance, and labeling and may be effective in treatment of patients during the COVID-19 pandemic. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic. Please visit The Hatzalah Patient Portal for additional information <https://hatzalahbaltimore.org/patient-portal/>