



## New Correctional Indication for Monoclonal Antibody (Regen-COV) for SARS-CoV2

August 24, 2021

Dear Correctional Administrator,

(Please also share this informational sheet with your facility health care provider)

On July 30, 2021, the FDA modified its Emergency Use Authorization (EUA) for Regen-COV, a medication used in the treatment of COVID-19 infection. The purpose of this informational sheet is to make sure you and your health care team are aware of a specific indication for the use of MCAB in correctional settings addressed in the modified EUA. This is not a guidance, or endorsement nor meant to establish a standard of care; it is provided for your information to address as your clinicians see fit.

### Background:

Regen-COV is a monoclonal antibody (MCAB) used in the management of the SARS-CoV-2 pandemic.

### New Indication:

Regen-COV is now approved under the EUA for use in correctional populations to *prevent* COVID infection under the following conditions:

- there is an occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting, **and**
- the patient being treated is not fully vaccinated or is not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination, **and**
- the patient being treated is at high risk for progression to severe COVID-19, including hospitalization or death (e.g., they have certain comorbidities)<sup>1</sup>.

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<sup>1</sup> The indications may be confusing because an early version of the FDA's Announcement of the new correctional indication was missing this third bulleted requirement. FDA has corrected the error.

### What does “in the same institutional setting” mean?

FDA did not define this further. The logic behind their recommendation is that COVID-19 infection can spread more easily in correctional settings than in the community. In consultation with your facility health care provider and/or local health jurisdiction officer, you’ll need to decide what the “same institutional setting” means by judging whether the risk of COVID-19 spreading from the person or persons with the infection is mostly limited to a cell, living unit, floor, building, etc.

### What is the purpose of medicating?

MCAbs are different from vaccines. Vaccines instruct the body’s immune system to produce the body’s own antibodies. MCAbs are manufactured antibodies. In both cases the antibodies target and attach to a specific part of the coronavirus, neutralizing it. However, because the vaccine has “taught” the body how to produce its own antibodies, the effect usually lasts much longer, whereas an injection of MCAbs only helps until the antibody is used up. So MCAbs are not a replacement for vaccination. Up until now, MCAb was used to treat high risk patients with mild to moderate symptoms from COVID-19 (but who were not sick enough to be in the hospital) to lower the chance of hospitalization or death. Based on a [new study](#) which prompted this EUA modification, MCAb reduces symptomatic COVID-19 infection by about 6 percentage points. However, the study was conducted among people in the community exposed to infection from others in their household. So, whether we will see the same, higher, or lower levels of protection in jails and prisons is still unknown.

### How do you obtain the medication?

You should use your usual mechanism for obtaining medications. If that is unsuccessful, you can request the medication directly from the sole distributor (<https://www.regencov.com/hcp/access>, click on “Order Regen-COV”).

### How much does it cost?

The medication is free.

### What is involved in administering the medication?

The medication is supposed to be administered as soon as possible after the occurrence of SARS-CoV-2 is identified in the institution. The manufacturer recommends intravenous administration, but states it can be given as a shot under the skin if necessary. Your provider may decide to give additional (smaller) doses every 4 weeks for the duration of the exposure. Your provider should review the complete [FDA Fact Sheet for Healthcare Providers](#) before ordering the medication, and should provide this [Fact Sheet for Patients](#) to patients they offer the medication to help these patients understand the potential risks and benefits.

### What is the significance of the drug’s “EUA” status?

The EUA approval of MCAb has the same significance as the EUA status granted to the COVID-19 vaccines we have been administering. It means that the FDA determined from growing evidence that the medication is reasonably safe and effective, in other words that patients can benefit from it. It is *not* in any way “experimental.”