St. Peter's Health

# REGEN-COV (casirivimab/imdevimab) for COVID-19

| | REGEN-COV |
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| What is it? | A monoclonal antibody (mAb) developed by Regeneron Pharmaceuticals in 2020 for COVID-19. Originally the FDA published an emergency use authorization (EUA) for REGEN-COV on November 21, 2020.<br><br>This medication is only approved for **outpatient** use to treat or prevent progression of COVID-19 disease in high-risk individuals with a positive COVID-19 test**.** |
| How does it work? | The COVID-19 virus attaches to the ACE-2 receptor on the surface of human cells and uses this protein for cellular entry. The virus achieves this using its spike protein located on its surface. Both mAbs contained in REGEN-COV bind to the spike protein on COVID-19 preventing the attachment to the ACE-2 receptor inhibiting viral entry into human cells. This prevents viral replication of COVID-19. |
| Who is eligible? | Patients who meet the following:<br>• A positive COVID-19 test<br>• Symptom onset of less than 10 days ago<br>• A high-risk condition (below) must be present. However, the presence of one of these conditions means they *can* get REGEN-COV under the EUA. It doesn't mean they *should* get REGEN-COV. Clinical judgement is required and availability is subject to local resources. |
| Criteria | • High risk conditions include one or more of the following: 65 years or older, obesity, pregnancy, chronic kidney disease (CKD), diabetes, immunosuppression, cardiovascular disease (CVD), lung disease, sickle cell disease, neurodevelopmental disorders, assistive breathing |
| Who is excluded? | Patients who meet one or more of the following:<br>• Hospitalized due to COVID-19<br>• Requires oxygen due to COVID-19<br>• If the patient is on baseline oxygen and they have an increase in oxygen demand due to COVID-19 |

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| Benefits | Reduction in progression of COVID-19 in high-risk individuals who are tested positive for COVID-19.<br><br>In clinical trials:<br>• Patients experienced shorter duration of symptoms after taking REGEN-COV (10 days vs 14 days with placebo)<br>• Patients treated with REGEN-COV had a 70% reduced risk of death due to COVID-19 compared to placebo |
| Risks | The risks are relatively unknown due to limited data on this medication. The only associated risk is hypersensitivity to the medication (0.2%). The EUA does mention a risk of possible clinical worsening, but it's not established whether this is due to the medication or COVID-19.<br><br>Other considerations should be taken into account with a risk-benefit analysis; the following considerations are not absolute contraindications based on the FDA's EUA.<br><br>Considerations before treatment:<br>• Pregnant or planning to become pregnant<br>• If the patient is breast feeding<br>• History of hypersensitivity reactions to monoclonal antibodies (not including REGEN-COV) |
| Dose | A one-time dose of 600mg/600mg casirivimab/imdevimab (REGEN-COV) via IV infusion<br><br>No renal or hepatic dose adjustment is indicated. |
| Adverse events | Hypersensitivity (0.2%)<br>Injection site reactions (4%)<br>Infusion reactions (Incidence not defined) |
| Contraindications | Hypersensitivity to REGEN-COV<br>Previous severe infusion related reactions (Ex: arrhythmia) |
| Warnings/Precautions | Hypersensitivity<br>Possible clinical worsening (unclear if caused by medication or COVID-19) |
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