**Monoclonal Antibody Summary**

Administration

* REGEN-COV is authorized for emergency use for the treatment of mild to moderate COVID-19 in adult and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.
  + The EUA does contain a list of high-risk conditions, but also allows a provider to use their clinical judgement to determine if an individual is considered high-risk for severe COVID-19.
  + For treatment, REGEN-COV can be given via **IV infusion followed by a 1 hour observation period**. If IV administration is not feasible, it **can be given subcutaneously**. The 1 hour observation period still applies.
  + **Treatment must be given within 10 days of symptom onset**, so early testing is critical.
* REGEN-COV is also authorized for emergency use as post-exposure prophylaxis in some patients who are exposed to COVID-19 even if they are not showing symptoms. People who are not fully vaccinated or who have immunocompromising conditions, including those taking immunosuppressive medications, and have either been exposed to COVID-19 or are at high risk of exposure due to where they live or work may qualify for preventative treatment.
  + For Post-exposure prophylaxis, REGEN-COV **can be given IV or subcutaneously** and the 1 hour observation period still applies.
* REGEN-COV can only be administered in settings where there is immediate access to medications to treat severe anaphylactic type reactions and the ability to activate EMS as necessary.
  + There is no set list of rescue medications that you must have on hand.

Ordering:

* Providers capable of adhering to the EUA, can order REGEN-COV directly from AmerisourceBergen (ABC) **at no cost** using this online order form: [https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8](https://urldefense.com/v3/__https:/app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8__;!!HYmSToo!NKKaMrwAmSWX69W5Ug4vbOpr9l2w5gUTbEeB4dP6v5UeDnMXlx9wBgfKeevuIwhPsSUj$)
* First time orders will be asked to submit medical licensure or NC Board of Pharmacy license information. There may be a 1-2 day delay for first time orders as they will have to setup an account for you.
* Orders are prioritized based on the “need by” date submitted with your request.
* **Product ships at refrigerated temps 2-8oC and should be stored refrigerated until preparation for administration**. REGEN-COV now comes in a co-formulated 10mL single dose vial.
* Minimum order quantity is 10 patient courses

Here is a link to the [Federal Monoclonal Antibody Playbook](https://urldefense.com/v3/__https:/www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/USG-COVID19-Tx-Playbook.pdf__;!!HYmSToo!NKKaMrwAmSWX69W5Ug4vbOpr9l2w5gUTbEeB4dP6v5UeDnMXlx9wBgfKeevuI4VAG9gn$). Starting on slide 18 includes readiness checklist, suggested supplies, roles and responsibilities needed onsite.

Additional Resources that you may find helpful:

* Most current Emergency Use Authorization (EUA) Fact Sheets:
  + [REGEN-COV EUA Fact Sheet for Healthcare Providers](https://urldefense.com/v3/__https:/www.fda.gov/media/145611/download__;!!HYmSToo!NKKaMrwAmSWX69W5Ug4vbOpr9l2w5gUTbEeB4dP6v5UeDnMXlx9wBgfKeevuI2e4Leq5$) (MUST READ as it contains all the requirements related to REGEN-COV Use)
  + REGEN-COV Fact Sheet to Patients, Parents and Caregivers: [English](https://urldefense.com/v3/__https:/www.fda.gov/media/145612/download__;!!HYmSToo!NKKaMrwAmSWX69W5Ug4vbOpr9l2w5gUTbEeB4dP6v5UeDnMXlx9wBgfKeevuI6lEA69E$) & [Spanish](https://urldefense.com/v3/__https:/www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-patient-spanish.pdf__;!!HYmSToo!NKKaMrwAmSWX69W5Ug4vbOpr9l2w5gUTbEeB4dP6v5UeDnMXlx9wBgfKeevuI7XblOrE$)
* [FDA statement about using REGEN-COV as post-exposure prophylaxis](https://urldefense.com/v3/__https:/www.fda.gov/drugs/drug-safety-and-availability/fda-authorizes-regen-cov-monoclonal-antibody-therapy-post-exposure-prophylaxis-prevention-covid-19__;!!HYmSToo!NKKaMrwAmSWX69W5Ug4vbOpr9l2w5gUTbEeB4dP6v5UeDnMXlx9wBgfKeevuI6Zgpr-9$) (REGEN-COV Authorized for PEP as of 7/30/21)
* [National Infusion Center Association (NICA) COVID-19 Therapy Locator Tool](https://urldefense.com/v3/__https:/covid.infusioncenter.org/__;!!HYmSToo!NKKaMrwAmSWX69W5Ug4vbOpr9l2w5gUTbEeB4dP6v5UeDnMXlx9wBgfKeevuI0U7gcbv$) and [instructions on how to claim your profile once it is added to the site](https://urldefense.com/v3/__http:/infusioncenter.org/wp-content/uploads/2021/03/How-To-Use-NICA-Locator_Providers_LinkedVersion.pdf__;!!HYmSToo!NKKaMrwAmSWX69W5Ug4vbOpr9l2w5gUTbEeB4dP6v5UeDnMXlx9wBgfKeevuI0ouQRli$) which happens automatically after placing your first order.
  + This is the locator tool that we point the general public to in all of our monoclonal antibody information.
* [NICA Best practices](https://urldefense.com/v3/__https:/infusioncenter.org/nica-monoclonal-antibody-therapies-best-practices/__;!!HYmSToo!NKKaMrwAmSWX69W5Ug4vbOpr9l2w5gUTbEeB4dP6v5UeDnMXlx9wBgfKeevuI6PqzoXg$)

Reimbursement Information:

* [Centers for Medicare & Medicaid services mAb website](https://urldefense.com/v3/__https:/www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion__;!!HYmSToo!NKKaMrwAmSWX69W5Ug4vbOpr9l2w5gUTbEeB4dP6v5UeDnMXlx9wBgfKeevuI2b0XoQ8$) – contains billing codes and reimbursement rates
* Since the product itself is provided free of charge, you cannot charge the patient for the medication. However, you can bill insurance for the administration fee.
* [HRSA reimbursement program for the uninsured](https://www.hrsa.gov/CovidUninsuredClaim).

Utilization Reporting:

* NC DHHS currently collects mAb inventory and use information weekly from all mAb providers via online survey every Wednesday. Here is what the survey currently looks like: [https://surveymax.dhhs.state.nc.us/TakeSurvey.aspx?SurveyID=therapeutics#](https://urldefense.com/v3/__https:/surveymax.dhhs.state.nc.us/TakeSurvey.aspx?SurveyID=therapeutics*__;Iw!!HYmSToo!NKKaMrwAmSWX69W5Ug4vbOpr9l2w5gUTbEeB4dP6v5UeDnMXlx9wBgfKeevuIxtcypmP$)
* I email the survey link to all providers every Wednesday with a reminder to report.
* The Federal Government also collects this information through their system called Teletracking and they will reach out to you via email to sign up for their system after placing your first order.