Health

AUGUSTA UNIVERSITY

COVID-19

Therapeutic Monoclonal Antibody Infusion

Provider Referral

Updated 8/16/21

AU Health is offering Therapeutic Monoclonal Antibody Infusions for high risk patients recently diagnosed with COVID-19 and is currently administering REGEN-COV™ (casirivimab and imdevimab)

Therapeutic Monoclonal Antibody Infusions must be administered within 10 days of symptom onset (preferably <5 days) and as soon as possible after a positive viral test for SARS-CoV-2.

Referral Process:

1. All patients must have a provider referral.

2. Please verify that your patient meets the inclusion criteria and does not meet the exclusion criteria on the next page, then fax the clinical screening worksheet and the patient's positive COVID-19 results to **706-721-9445.**

3. For any questions around scheduling or to speak with an AU Health scheduler, please call **706-721-9449 (8a-5p)**.

4. Upon receipt of the referral, the patient will be scheduled for a virtual care appointment with an AU Health provider to verify infusion appropriateness.

5. If the patient meets clinical appropriateness, they will be scheduled for an infusion appointment at AU Health.

6. If the patient does not meet the clinical appropriateness after the virtual care appointment is conducted, the referring provider will be notified by AU Health and the patient will be informed during the virtual care visit.

Referral Form – Therapeutic Monoclonal Antibody Infusion

Currently Using Casirivimab/Imdevimab

Please complete & fax to: 706-721-9445

***Please fill out form in its entirety and include a copy of patient's COVID positive result**. A positive test, along with specific inclusion criteria, are required. After receipt of the referral, patients will receive a call to schedule a virtual screening and infusion appointment, if appropriate.*

Patient Name (Last, First, MI)_____

DOB (mm/dd/yyyy)_____

Patient Mobile # (to initiate Virtual Care visit)_____

Referring Provider_____

Referring Provider Contact #_____

Referring Practice Name_____

Clinical Screening Worksheet:

Please answer each section. If the worksheet is not complete, the scheduling team will contact the practice to obtain the information to process the referral request.

In order to meet criteria for therapeutic monoclonal antibody infusion, the patient must either be >65 years old, or meet one of the clinical indications on the next page

1. **Positive COVID-19 test result (circle one): YES or NO** ***(If NO, skip to the bottom of the next page for post exposure prophylaxis criteria)***
   - Date of COVID-19 test: (mm/dd/yyyy) _____
   - **RESULT MUST BE INCLUDED WITH REFERRAL. CHECK IF RESULT IS INCLUDED** ☐
     - If there is no positive test, patient is not eligible for treatment
2. **Symptom Onset within last 10 days (circle one): YES or NO**
   - Date of Symptom Onset: (mm/dd/yyyy) _____
     - If no, patient is **not eligible** to receive treatment
     - If yes, continue to question 3.
3. **Patient Weight:** _____ lbs/ kgs
   - If patient weighs less than 40 kg (88 lbs), patient is **not eligible** for treatment
4. **Patient Age:** _____ years
   - If 65 years or older, patient is **eligible**
   - If less than 12 years old, patient is **not eligible** for treatment

5. **The patient is <u>at least 12 years old</u>, and has at least one of the following conditions**

☐ Pregnancy
☐ Chronic Kidney Disease (CKD) [see appendix]
☐ Diabetes (type 1 or type 2)
☐ Immunosuppressive disease [see appendix]
☐ Receiving Immunosuppressive treatment (chemotherapy, transplant immunosuppressant, immune modulators such as Rituximab, etc...)
☐ Cardiovascular disease (CVD) [see appendix]
☐ Congenital or acquired heart disease
☐ Hypertension (HTN)
☐ Chronic Obstructive Pulmonary Disease (COPD) or other chronic respiratory disease [see appendix]
☐ Asthma, reactive airway or other chronic respiratory disease requiring daily medication
☐ Sickle Cell Disease
☐ Neurodevelopmental diseases (e.g. cerebral palsy) [see appendix]
☐ A medical-related technological dependence (e.g. tracheostomy, gastrostomy or positive pressure ventilation not related to COVID-19)
☐ If Age > 17, Body Mass Index (BMI) >25 Height: _____ft/m Weight: _____ lbs/kg
BMI = Weight in kilograms / [Height in meters] ²
Calculator**:** **https://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm**

BMI = _____

☐ If Age 12-17, Body Mass Index (BMI) > 85% for their age

- Boys: https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm#males
- Girls: https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm#females

- ***If any of the above are true, the patient is eligible for treatment***

☐ Other medical condition or factor that places the patient at High Risk_____

- Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progressing to severe COVID-19 and authorization 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 progressing to severe COVID-19, 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.

6. **Qualifies for Post Exposure Prophylaxis (circle one): YES or NO**

- Not fully vaccinated or who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications)
  - **and** have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per Centers for Disease Control and Prevention (CDC)—someone who was within 6 feet for a cumulative total of 15 minutes or more over a 24-hour period
  - **or** who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes, prisons

Referring Provider Signature_____

Appendix

Eligible medical conditions (including but not limited to)

Chronic Kidney Disease

- Chronic Kidney Disease (CKD)/(Chronic renal insufficiency (CRI)
- Dialysis
- End Stage Renal Disease (ESRD)
- Glomerulonephritis (GN)
- Nephrotic syndrome
- Polycystic kidney disease (PCKD)

Immunosuppressive Disease

- AIDS or CD4 count ‹200
- Complement deficiency
- Grafts-vs-Host disease (GVHD)
- HIV Infection
- Immunoglobulin deficiency/Immunodeficiency
- Immunosuppressive therapy (within the last 12 months)
- Leukemia
- Lymphoma (Hodgkins/Non-Hodgkins (NHL))
- Metastatic cancer
- Multiple Myeloma
- Solid organ malignancy
- Steroid therapy (within past 2 weeks)
- Bone marrow transplant (BMT) or peripheral stem cell transplant (PSCT)
- Solid organ transplant

Chronic Respiratory Disease

- Active Tuberculosis (TB)
- Asbestosis
- Asthma/Reactive airway disease
- Bronchiectasis
- Bronchiolitis obliterans
- Chronic bronchitis
- Chronic respiratory failure
- Cystic Fibrosis
- Emphysema/Chronic obstructive pulmonary disease (COPD)
- Interstitial lung disease (ILD)
- Obstructive sleep apnea (OSA)
- Oxygen (O2) dependent
- Pulmonary fibrosis
- Restrictive lung disease
- Sarcoidosis

Cardiovascular Disease

- Aortic aneurysm
- Valvular heart disease or valve replacement
- Atherosclerotic cardiovascular disease (ASCVD)
- Atrial fibrillation (AFib)
- Atrioventricular (AV) blocks
- Automated implantable devices (AID/AICD)/Pacemaker
- Bundle branch block (BBB, LBBB, RBBB)
- Cardiomyopathy
- Carotid stenosis
- Stroke
- Congenital heart disease
- Coronary artery bypass grafting (CABG)
- Coronary artery disease (CAD)
- Deep vein thrombosis (DVT)
- Congestive Heart Failure (CHF)
- Myocardial infarction (MI)
- Peripheral artery disease (PAD)
- Peripheral vascular disease (PVD)
- Pulmonary embolism (PE)
- Pulmonary hypertension (PHTN)
- Transient ischemic attack (TIA)
- History of Ventricular fibrillation (VF, VFib)
- History of Ventricular tachycardia (VT, VTach)

Neurodevelopmental Disease

- Cerebral palsy
- Down Syndrome/Trisomy 21
- Edward's Syndrome/Trisomy 18
- Epilepsy/Seizure/Seizure disorder
- Mitochondrial disorder
- Muscular dystrophy
- Neural tube defects/Spina bifida

Day of Infusion

1. When the patient arrives on the day of infusion, the patient should remain in their car and call the clinic provided telephone number. Someone will meet the patient at their car and escort the patient to the infusion suite.

2. The patient will be reassessed by a provider for changes in clinical condition upon arrival.

3. No guests will be allowed in the infusion suite unless the patient requires a caregiver at home or is a minor child.

4. The infusion will take around one hour with an additional one hour of patient monitoring after the infusion for a 3 hour total visit.

Patient Reminders

- Directions to the patient drop off area will be provided upon scheduling.
- Please arrive on time and expect to be in clinic infusion suite for 3 hours, which includes a clinical reassessment for infusion appropriateness, medication prep time, infusion, and post-infusion patient monitoring.
- Patient must wear a mask covering their nose and mouth at all times.
- Patient should bring a small non-perishable snack from home, reading material and/or a personal device due to the length of the procedure and observation.

COVID-19 Vaccine for Patients & Provider Information

- Patients who have already received the COVID-19 vaccination are eligible to receive the infusion treatment if they meet the inclusion criteria
- For patients who receive the infusion treatment and have not received the vaccination, they should not receive the vaccine for 90 days following the infusion treatment.

FACT SHEET FOR PATIENTS, PARENTS AND CAREGIVERS EMERGENCY USE AUTHORIZATION (EUA) OF REGEN-COV™ (casirivimab and imdevimab) FOR CORONAVIRUS DISEASE 2019 (COVID-19)

You are being given a medicine called **REGEN-COV (casirivimab and imdevimab)** for the treatment or post-exposure prevention of coronavirus disease 2019 (COVID-19). SARS-CoV-2 is the virus that causes COVID-19. This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking REGEN-COV.

Receiving REGEN-COV may benefit certain people with COVID-19 and may help prevent certain people who have been exposed to someone who is infected with SARS-CoV-2 from getting SARS-CoV-2 infection, or may prevent certain people who are at high risk of exposure to someone who is infected with SARS-CoV-2 from getting SARS-CoV-2 infection.

Read this Fact Sheet for information about REGEN-COV. Talk to your healthcare provider if you have questions. It is your choice to receive REGEN-COV or stop at any time.

WHAT IS COVID-19?

COVID-19 is caused by a virus called a coronavirus, SARS-CoV-2. People can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can happen and may cause some of your other medical conditions to become worse. People of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example, and other conditions including obesity, seem to be at higher risk of being hospitalized for COVID-19. Older age, with or without other conditions, also places people at higher risk of being hospitalized for COVID- 19.

WHAT ARE THE SYMPTOMS OF COVID-19?

The symptoms of COVID-19 include fever, cough, and shortness of breath, which may appear 2 to 14 days after exposure. Serious illness including breathing problems can occur and may cause your other medical conditions to become worse.

WHAT IS REGEN-COV (casirivimab and imdevimab)?

REGEN-COV is an investigational medicine used in adults and adolescents (12 years of age and older who weigh at least 88 pounds (40 kg)) who are at high risk for severe COVID-19, including hospitalization or death for:

- treatment of mild to moderate symptoms of COVID-19
- post-exposure prevention of COVID-19 in persons who are:
    - not fully vaccinated against COVID-19 (Individuals are considered to be fully vaccinated 2 weeks after their second vaccine dose in a 2-dose series [such as the Pfizer or Moderna vaccines], or 2 weeks after a single-dose vaccine [such as Johnson & Johnson's Janssen vaccine]), **or**,
    - are not expected to build up enough of an immune response to the complete COVID-19 vaccination (for example, someone with immunocompromising conditions, including someone who is taking immunosuppressive medications),

    and

    - have been exposed to someone who is infected with SARS-CoV-2. Close contact with someone who is infected with SARS-CoV-2 is defined as being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (hugging or kissing, for example), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (sneezing or coughing, for example). For additional details, go to https://www.cdc.gov/coronavirus/2019-ncov/if-you-are- sick/quarantine.html, **or**

- someone who is at high risk of being exposed to someone who is infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, as nursing homes, prisons,).

REGEN-COV is investigational because it is still being studied. There is limited information known about the safety and effectiveness of using REGEN-COV to treat people with COVID-19 or to prevent COVID-19 in people who are at high risk of being exposed to someone who is infected with SARS-CoV-2. REGEN-COV is not authorized for pre-exposure prophylaxis for prevention of COVID-19.

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

WHO SHOULD NOT TAKE REGEN-COV?

Do not take REGEN-COV if you have had a severe allergic reaction to REGEN-COV.

WHAT SHOULD I TELL MY HEALTH CARE PROVIDER BEFORE I RECEIVE REGEN-COV?
Tell your healthcare provider about all of your medical conditions, including if you:

- Have any allergies
- Have had a severe allergic reaction including anaphylaxis to REGEN-COV previously
- Have received a COVID-19 vaccine.
- Have any serious illnesses
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Are taking any medications (prescription, over-the-counter, vitamins, and herbal products)

HOW WILL I RECEIVE REGEN-COV (casirivimab and imdevimab)?

- REGEN-COV consists of two investigational medicines, casirivimab and imdevimab, given together at the same time through a vein (intravenous or IV) or injected in the tissue just under the skin (subcutaneous injections). **Your healthcare provider will determine the most appropriate way for you to be given REGEN-COV.**

- Treatment: If you are receiving an intravenous infusion, the infusion will take 20 to 50 minutes or longer. Your healthcare provider will determine the duration of your infusion.
    - If your healthcare provider determines that you are unable to receive REGEN- COV as an intravenous infusion which would lead to a delay in treatment, then as an alternative, REGEN-COV can be given in the form of subcutaneous injections. If you are receiving subcutaneous injections, your dose will be provided as multiple injections given in separate locations around the same time.
- Post-exposure prevention: If you are receiving subcutaneous injections, your dose will be provided as multiple injections given in separate locations around the same time. If you are receiving an intravenous infusion, the infusion will take 20 to 50 minutes or longer.
    - After the initial dose, if your healthcare provider determines that you need to receive additional doses of REGEN-COV for ongoing protection, the additional intravenous or subcutaneous doses would be administered monthly.

WHAT ARE THE IMPORTANT POSSIBLE SIDE EFFECTS OF REGEN-COV (casirivimab and imdevimab)?
Possible side effects of REGEN-COV are:

- Allergic reactions. Allergic reactions can happen during and after infusion or injection of REGEN-COV. Tell your healthcare provider right away or seek immediate medical attention if you get any of the following signs and symptoms of allergic reactions: fever, chills, nausea, headache, shortness of breath, low or high blood pressure, rapid or slow heart rate, chest discomfort or pain, weakness, confusion, feeling tired, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, feeling faint, dizziness and sweating. These reactions may be severe or life threatening.
- Worsening symptoms after treatment: You may experience new or worsening symptoms after infusion or injection, including fever, difficulty breathing, rapid or slow heart rate, tiredness, weakness or confusion. If these symptoms occur, contact your healthcare provider or seek immediate medical attention as some of these symptoms have required hospitalization. It is unknown if these symptoms are related to treatment or are due to the progression of COVID-19.

The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site. The side effects of getting any medicine by subcutaneous injection may include pain, bruising of the skin, soreness, swelling, and possible infection at the injection site.

These are not all the possible side effects of REGEN-COV. Not a lot of people have been given REGEN-COV. Serious and unexpected side effects may happen. REGEN-COV is still being studied so it is possible that all of the risks are not known at this time.

It is possible that REGEN-COV could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, REGEN-COV may reduce your body's immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks. Talk to your healthcare provider if you have any questions.

WHAT OTHER TREATMENT CHOICES ARE THERE?

Like REGEN-COV (casirivimab and imdevimab), FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.fda.gov/emergency- preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use- authorization for information on the emergency use of other medicines that are not approved by FDA that are used to treat people with COVID-19. Your healthcare provider may talk with you about clinical trials you may be eligible for.

It is your choice to be treated or not to be treated with REGEN-COV. Should you decide not to receive REGEN-COV or stop it at any time, it will not change your standard medical care.

WHAT OTHER PREVENTION CHOICES ARE THERE?

Vaccines to prevent COVID-19 are also available under Emergency Use Authorization. Use of REGEN-COV does not replace vaccination against COVID-19. REGEN-COV is not authorized for pre-exposure prophylaxis for prevention of COVID-19.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

There is limited experience using REGEN-COV (casirivimab and imdevimab) in pregnant women or breastfeeding mothers. For a mother and unborn baby, the benefit of receiving REGEN-COV may be greater than the risk of using the product. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

HOW DO I REPORT SIDE EFFECTS WITH REGEN-COV (casirivimab and imdevimab)?
Tell your healthcare provider right away if you have any side effect that bothers you or does not go away.

Report side effects to **FDA MedWatch** at www.fda.gov/medwatch or call 1-800-FDA-1088 or call 1-844-734-6643.

HOW CAN I LEARN MORE?

- Ask your health care provider.
- Visit www.REGENCOV.com
- Visit https://www.covid19treatmentguidelines.nih.gov/
- Contact your local or state public health department.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made REGEN-COV (casirivimab and imdevimab) 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 product. In issuing an EUA under the COVID-19 public health emergency, the FDA must determine, among other things, that based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective for diagnosing, treating, or preventing COVID-19, or a serious or life-threatening disease or condition caused by COVID-19; that the known and potential benefits of the product, when used to diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved and available alternatives. All of these criteria must be met to allow for the medicine to be used in the treatment of COVID-19 or prevention of COVID-19 during the COVID-19 pandemic.

The EUA for REGEN-COV is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Manufactured by:
Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, NY 10591-6707