Health

AUGUSTA UNIVERSITY

COVID-19 Therapeutic Monoclonal Antibody Provider Referral

Updated 4/22/21

AU Health is now offering COVID-19 Therapeutic Monoclonal Antibody for high risk patients recently diagnosed with COVID-19.

COVID-19 Therapeutic Monoclonal Antibody 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**.

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 - COVID-19 Therapeutic Monoclonal Antibody Infusion

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 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**
   - 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. **Does the patient have any of the following conditions?**

☐ 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...)

☐ Body Mass Index (BMI) ≥35 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 any of the above are true, the patient is *eligible* for treatment**

6. **If the patient is 55-64 years, do they have any of the following conditions?**

☐ Cardiovascular disease (CVD) [see appendix]

☐ Hypertension (HTN)

☐ Chronic Obstructive Pulmonary Disease (COPD) or other chronic respiratory disease [see appendix]

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

7. **If the patient is 12-17 years, do they have any of the following conditions?**

☐ Sickle Cell Disease

☐ Congenital or acquired heart disease

☐ Neurodevelopmental diseases (e.g. cerebral palsy) [see appendix]

☐ Asthma, reactive airway or other chronic respiratory disease requiring daily medication

☐ A medical-related technological dependence (e.g. tracheostomy, gastrostomy or positive pressure ventilation not related to COVID-19)

☐ BMI ≥ 85th Percentile 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, patient is *eligible* for treatment**

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 3-4 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 3-4 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 COVID-19 Therapeutic Monoclonal Antibody for Coronavirus Disease 2019
(COVID-19)

You are being given a medicine called **COVID-19 Therapeutic Monoclonal Antibody** for the treatment of coronavirus disease 2019 (COVID- 19). This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking COVID-19 Therapeutic Monoclonal Antibody, which you may receive.

Receiving COVID-19 Therapeutic Monoclonal Antibody may benefit certain people with COVID-19.

Read this Fact Sheet for information about COVID-19 Therapeutic Monoclonal Antibody. Talk to your healthcare provider if you have questions. It is your choice to receive COVID-19 Therapeutic Monoclonal Antibody or stop it at any time.

What is COVID-19?
COVID-19 is caused by a virus called a coronavirus. 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, seem to be 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.

COVID-19 Therapeutic Monoclonal Antibody 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. COVID-19 Therapeutic Monoclonal Antibody is investigational because it is still being studied. There is limited information known about the safety or effectiveness of using COVID-19 Therapeutic Monoclonal Antibody to treat people with COVID-19. The FDA has authorized the emergency use of COVID-19 Therapeutic Monoclonal Antibody 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.

How does COVID-19 Therapeutic Monoclonal Antibody work?
COVID-19 Therapeutic Monoclonal Antibody works by binding to proteins on the outer layer of the COVID-19 virus and preventing the virus from binding to certain receptors on your cells. This prevents the virus from being able to enter your cells and create more virus.

What are the potential benefits?
COVID-19 Therapeutic Monoclonal Antibody is still being studied so we do not know all of the potential risks or benefits that may come from receiving the drug. From what the scientists studying the drug have observed so far, COVID-19 Therapeutic Monoclonal Antibody may help prevent hospital admissions in patients that have risk factors for developing a severe case of COVID-19. COVID-19 Therapeutic Monoclonal Antibody may also slightly decrease the severity of COVID-19 infection if given early in the course of the disease.

Does COVID-19 Therapeutic Monoclonal Antibody prevent me from getting COVID-19 again?
No, COVID-19 Therapeutic Monoclonal Antibody does not prevent you from getting infected with COVID-19 again. It is only helps with the treatment of patients that currently have the virus. Though you will likely have some natural immunity after your COVID-19 infection resolves, we do not know how long this will last and it is still possible to get infected with the virus again. For this reason it is very important to get the COVID-19 vaccine as soon as you are eligible to receive it.

What should I tell my healthcare provider before I receive COVID-19 Therapeutic Monoclonal Antibody?

- Have any allergies
- 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?
COVID-19 Therapeutic Monoclonal Antibody is given to you as a one-time infusion through a vein (intravenous or IV). The infusion will last about one hour. We will keep you at the clinic for another hour after your infusion so that we can monitor you to ensure if a rare side effect does develop, we can treat you.

What are the possible side effects of COVID-19 Therapeutic Monoclonal Antibody?
Since COVID-19 Therapeutic Monoclonal Antibody is still being studied, we do not know all of the potential side effects that could occur. Most of the side effects that have been seen so far have been mild. The most common side effects observed include nausea (4%), dizziness (3%), and diarrhea (3%) during and soon after the infusion.
Other possible side effects of COVID-19 Therapeutic Monoclonal Antibody are:
Allergic reactions. Though rare, allergic reactions can happen during and after infusion with COVID-19 Therapeutic Monoclonal Antibody. Tell your healthcare provider right away if you get any of the following signs and symptoms of allergic reactions: fever, chills, nausea, headache, shortness of breath, low blood pressure, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, and dizziness, injection site reactions. The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, and swelling. About 2% of patients in the study of COVID-19 Therapeutic Monoclonal Antibody have experienced these reactions. If it happens, this should resolve quickly. If the redness, swelling, and pain does not resolve quickly, contact your healthcare provider.
These are not all the possible side effects of COVID-19 Therapeutic Monoclonal Antibody. Serious and unexpected side effects may happen. It is possible that it could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, it 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 COVID-19 Therapeutic Monoclonal Antibody, FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.covid19treatmentguidelines.nih.gov/ for information on the emergency use of other medicines that are not approved by FDA 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 COVID-19 Therapeutic Monoclonal Antibody. Should you decide not to receive COVID-19 Therapeutic Monoclonal Antibody or stop it at any time, it will not change your standard medical care.

What if I am pregnant or breastfeeding?
There is limited experience treating pregnant women or breastfeeding mothers with COVID-19 Therapeutic Monoclonal Antibody. For a mother and unborn baby, the benefit of receiving COVID-19 Therapeutic Monoclonal Antibody may be greater than the risk from the treatment. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

How do I report side effects with COVID-19 Therapeutic Monoclonal Antibody?
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, call 1-800-FDA-1088, or contact Eli Lilly and Company at 1-855-LillyC19 (1-855-545-5921).

How can I learn more?

What is an Emergency Use Authorization (EUA)?
The United States FDA has made COVID-19 Therapeutic Monoclonal Antibody 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.

COVID-19 Therapeutic Monoclonal Antibody 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.

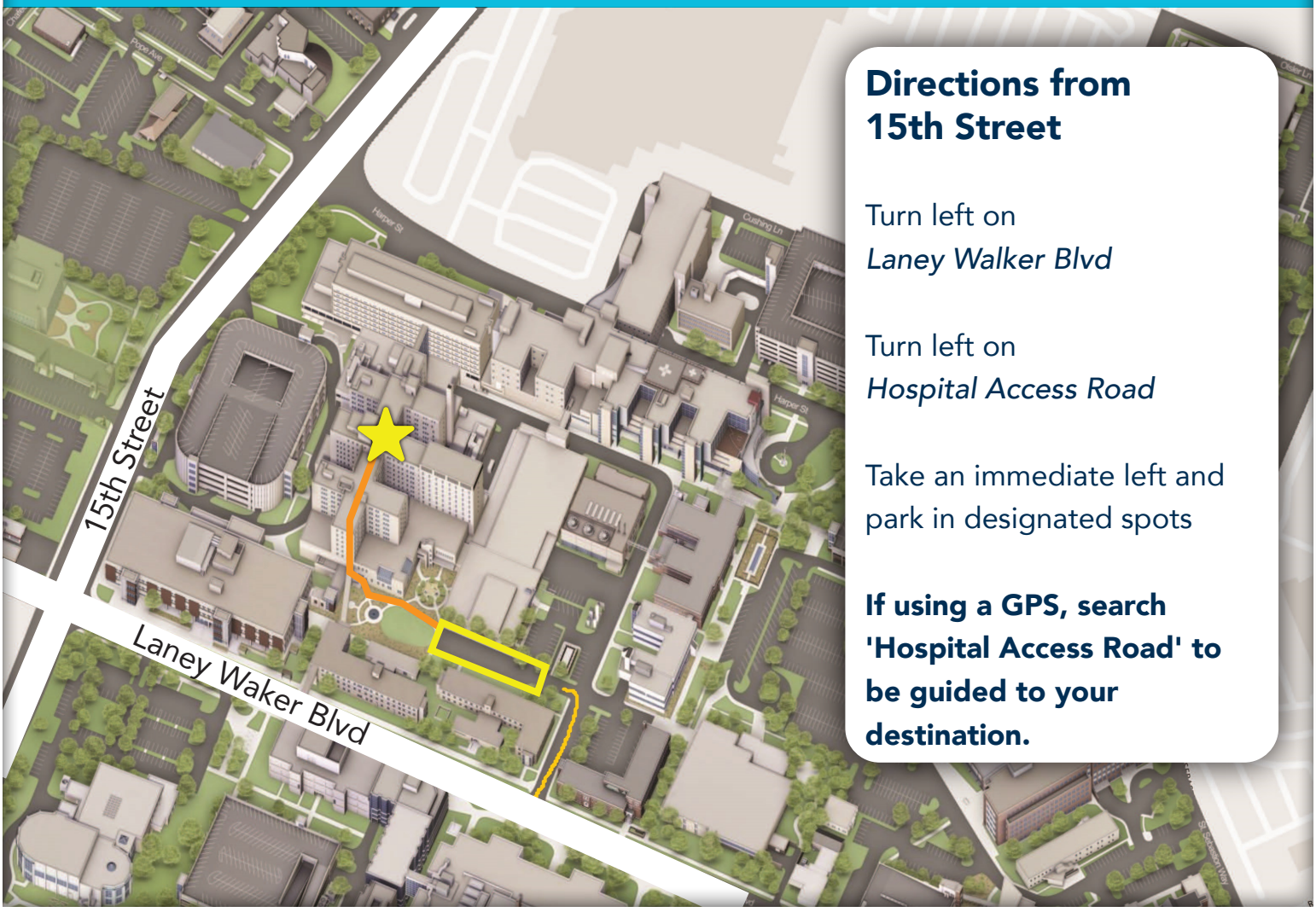
The EUA for COVID-19 Therapeutic Monoclonal Antibody is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the product may no longer be used).

Literature issued November 2020
Eli Lilly and Company, Indianapolis, IN 46285, USA

Health
AUGUSTA UNIVERSITY

Monoclonal Antibody Infusion Treatment Clinic Location

Park in the designated parking spots indicated by the yellow square, and call the number provided by appointment schedulers. You will be escorted from the parking lot to your infusion treatment.



Directions from 15th Street

Turn left on
Laney Walker Blvd

Turn left on
Hospital Access Road

Take an immediate left and park in designated spots

If using a GPS, search 'Hospital Access Road' to be guided to your destination.