BRING BACK LOUISIANA

LOUISIANA DEPARTMENT OF HEALTH

FAQS MONOCLONAL ANTIBODY TREATMENT FOR COVID-19

Updated: 8/23/2021

In November 2020, the U.S. Food and Drug Administration (FDA) issued Emergency Use Authorizations (EUA) permitting the use of monoclonal antibodies. Louisiana received its first allocation of monoclonal antibodies on November 12, 2020, and began administering to positive, symptomatic patients immediately. Louisiana was recognized by the Trump administration for being proactive in administering monoclonal antibody treatments ahead of other states.

Monoclonal antibodies are permitted for the treatment of mild to moderate COVID-19 in outpatient adult and pediatric patients. The EUAs for these treatments do not authorize their use for patients who are hospitalized due to COVID-19 or who require oxygen therapy due to COVID-19.

Patients with a positive COVID-19 viral test should speak with a healthcare provider - their own or an urgent care, community clinic, etc. - to determine whether they are eligible for monoclonal antibody treatment and to discuss potential benefits and side effects. Governor Edwards, the Louisiana Department of Health and healthcare providers across the state have promoted monoclonal antibodies since November 2020. Especially in a COVID-19 surge it is important to do whatever we can to expand access and that is precisely why we asked our federal partners to deploy paramedics to our facilities. However, monoclonal antibodies alone will not pave the way out of this pandemic; COVID-19 vaccinations will.

WHAT ARE MONOCLONAL ANTIBODIES (MABS) AND HOW DO THEY WORK?

An antibody is a protein that the body's immune system makes to fight off viruses and other foreign substances. MAbs are man-made antibodies produced in a laboratory that can mimic the human immune system response to infection. Each of the three drugs given an EUA are designed to block viral attachment and entry into human cells, thus neutralizing the virus that causes COVID-19.

HOW ARE MABS GIVEN?

MAbs must be given by intravenous (IV) infusion or subcutaneous injection. Therefore, mAbs may only be administered in settings in which healthcare providers have immediate access to medications to treat severe infusion reactions, such as allergic reaction, and the ability to activate the emergency medical system, as necessary.

WHO MAY RECEIVE MABS?

Under the terms of the EUAs, mAbs may be used for the treatment of mild to moderate COVID-19 in adults and pediatric patients who meet all of the following:

- Have a positive test for SARS-CoV-2 (molecular/PCR or antigen)
- Are within 10 days of the start of their symptoms
- Are at least 12 years of age or older and weigh at least 40 kilograms (88 pounds)
- Are at a high risk for progressing to severe COVID-19 and/or hospitalization

WHO IS CONSIDERED "HIGH RISK"?

High risk for progressing to severe COVID-19 and/or hospitalization is defined as patients who meet at least one of the following criteria:

- Older age (age ≥65 years of age)
- Obesity or being overweight (BMI >25 kg/m2, or if age 12-17, have BMI ≥85th percentile for their age and gender based on CDC growth charts, *https://www.cdc.gov/growthcharts/clinical_charts.htm)*
- Pregnancy
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung diseases (e.g., chronic obstructive pulmonary disease, moderate-to-severe asthma, interstitial lung disease, cystic fibrosis and pulmonary hypertension)
- Sickle cell disease
- Neurodevelopmental disorders (e.g., cerebral palsy) or other conditions that confer medical complexity (e.g., genetic or metabolic syndromes and severe congenital anomalies)
- Having a medical-related technological dependence (e.g., tracheostomy, gastrostomy, or positive pressure ventilation not related to COVID 19)

Other medical conditions or factors (e.g., race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19 and authorization of REGEN-COV 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 progression to severe COVID-19, see the CDC website: *https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/assessing-risk-factors.html*

Healthcare providers should consider the benefit-risk for an individual patient.

CAN INDIVIDUALS WHO ARE PREGNANT OR BREASTFEEDING RECEIVE MABS?

Insufficient data exist to fully evaluate mAbs in pregnant and breastfeeding women, although pregnancy is recognized as a high-risk condition for the progression to severe COVID-19 disease or death and is listed as a potential indication for mABs. Individuals who are pregnant, or are breastfeeding and otherwise meet treatment criteria, should discuss the use of mAbs with their physician.

WHO SHOULD NOT RECEIVE MABS?

MAbs may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation. Under the terms of the EUA mAbs are not authorized for use in patients who meet any of the following:

- Are hospitalized due to COVID-19
- Require oxygen therapy due to COVID-19
- Require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity

WHAT IS THE COST TO PATIENTS?

There is no cost to patients as the medications are made available to providers at no cost. Providers can bill the patient's insurance carrier for a facility/service charge to the patient's insurance but they cannot bill patients.

WHAT IS THE COST TO PROVIDERS?

Insured Patients: The medications are made available at no cost to the provider. For their patients with insurance including Medicare and Medicaid, providers can bill for the office visit.

Uninsured Patients: For uninsured patients, the federal HRSA COVID-19 Coverage Assistance Fund was developed to reimburse providers for COVID-19 treatments including monoclonal antibody therapy. See this link for more information: *https://www.hrsa.gov/coviduninsuredclaim*

HOW DO I GET TREATED WITH MONOCLONAL ANTIBODY THERAPY?

Patients need to be referred by their doctor or other healthcare provider to a facility that offers mAb therapy such as a hospital or an infusion center. Those without a provider can be referred by an urgent care, community clinic, emergency department, hospitalist, etc.

Patients with a positive COVID-19 viral test should speak with their healthcare provider to determine whether they are eligible for mAb treatment and to discuss potential benefits and side effects.

HOW DO I FIND A MONOCLONAL ANTIBODY PROVIDER/LOCATION NEAR ME?

Patients need to be referred by their doctor or other healthcare provider to a facility that offers mAb therapy.

Searchable Map: The federal government has developed a searchable national map that show locations that have received shipments of monoclonal antibody therapeutics under FDA EUA authority, within the past several weeks. The scalable map is found at this link: *https://protect-public.hhs.gov/pages/therapeutics-distribution*

Telephone Hotline: A call center is available to answer questions and provide information related to monoclonal antibody therapeutic treatments at 1-877-332-6585 (English Language); 1-877-366-0310 (Spanish Language).

ARE MONOCLONAL ANTIBODY TREATMENTS OUR WAY OUT OF THE PANDEMIC?

No.

While mAb is effective at decreasing severe illness from COVID infection IF received within a couple of days of onset of symptoms, getting vaccinated against COVID-19 prevents severe illness with an extremely low percentage of vaccinated persons being infected and needing to be hospitalized, ultimately decreasing the necessity of using limited healthcare resources to care for them.

MAbs, like the Pfizer, Moderna and Johnson & Johnson vaccines, are utilized under an EUA. Unlike the vaccinations that have a 15-minute observation period post-inoculation, mAb takes a couple of hours to administer and observe for adverse reaction, tying up much needed healthcare staff who are already stretched too thin to evaluate a patient after receiving mAb rather than render care to hospitalized patients.

To date, more than two million Louisianans have been fully vaccinated with a drug that has received an EUA similar to mAb treatment, with only eight severe reactions causing short hospital stays and zero deaths.