

## JB Pritzker, Governor

# COVID-19

## Ngozi O. Ezike, MD, Director

8/23/2021

## **MEMORANDUM**

- TO: Monoclonal Antibody Therapy Provider Sites in Illinois Hospital and Infusion Site Administrators Hospital and Infusion site Pharmacists Regional Hospital Coordinating Centers Local Health Departments
- FROM: Ashley Thoele, MSN, MBA, RN Division Chief, EMS and Highway Safety Office of Preparedness and Response

#### RE: Monoclonal Antibody Therapy Administration Toolkit

Monoclonal antibody therapy is a treatment option for mild to moderate COVID-19 illness for non-hospitalized people and is a way to prevent the potential progression to severe illness or hospitalization. IDPH continues to encourage Healthcare providers such as primary care offices, outpatient clinics, urgent care centers, infusion centers, dialysis centers, home health services, long term care facilities, and hospitals to assess their capabilities to provide this treatment to their patients quickly after they have been identified as having COVID-19 and are determined to be high-risk for severe illness or hospitalization. The two current therapeutics available for use Illinois are <u>REGEN-COV</u> and <u>sotrovimab</u>. Sotrovimab is available directly from <u>GlaxoSmithKline</u>. REGEN-COV is available for <u>ordering</u> from AmeriSourceBergen and is the most commonly used.

There is ample supply available for patient use. The resources and tools located at the websites below can assist healthcare providers in determining their own capabilities to provide this service or finding a location near them that does provide the service or has supply available.

#### **Routes of Administration**

Currently the approved routes of administration under the EUA are via Intravenous Therapy (IV) and Subcutaneous injection (SubQ).

#### Post-Exposure Prophylaxis

The REGEN-COV Emergency Use Authorization (EUA) has been expanded to include postexposure prophylaxis. FDA's authorization of a therapeutic product for post-exposure prophylaxis is a significant advancement in the COVID-19 response that supplements vaccination for disease prevention. Please refer to the <u>updated Fact Sheets</u> for full details about dosing and administration.

### **High Risk Populations**

COVID-19 symptoms can vary widely. While others show minimal symptoms, some may see illness progress and experience very serious disease. This risk may increase in people who are older than 12 years of age and who are older and people with serious health problems such as heart or lung conditions, weakened immune systems, obesity, or diabetes. Consideration should be made for any medical condition or other factor, including race or ethnicity, that puts someone at higher risk of progression to severe illness.

Health care providers should assess the need to provide monoclonal antibody therapy access in areas where there is a high concentration of high-risk individuals in their communities.

### Information for Healthcare providers and uninsured patients

The Health Resources and Services Administration (HRSA) has developed an <u>information</u> <u>resource</u> for patients who do not have health insurance and need services or treatments related to a COVID-19 illness. A federal Uninsured Program pays for COVID-19 services provided to anyone without health insurance. This is regardless of their immigration status. Testing, treatment, or vaccinations paid for by the federal government will not affect anyone's immigration status or be shared with immigration services. Additional information is available for <u>healthcare providers</u> and <u>patients</u>.

#### Information and Distributive Resources

- IDPH Website: <u>Monoclonal Antibody Treatment</u> (update in progress)
- HHS ASPR's Website: <u>Monoclonal Antibody Therapeutics</u>
  - This site includes information for infusion sites, healthcare professionals, and patients.
  - Administration Site <u>Checklist</u>
  - Moncolonal Antibody Therapy <u>Playbook</u>
  - o Mabs Calculator
- > COMBATCOVID: Monoclonal Antibodies for High-risk COVID-19 positive patients
- <u>Centers for Medicare & Medicaid Services</u> Medicare Part B Payment for COVID-19 Monoclonal Antibodies during a Public Health Emergency

## Treatment/Infusion Site Locator Tools

- Healthcare providers and the public can access the links below to determine the infusion site location closest to them. There is also a toll-free number for assistance.
  - Visit the <u>HHS Protect Infusion Site Locator</u>, the <u>National Infusion Center</u> <u>Association Locator</u>

 Call the Combat COVID Monoclonal Antibodies Call Center at 1-877-332-6585 for English or 1-877-366-0310 for Spanish

#### **COVID-19 Monoclonal Antibody Therapeutics Communications Toolkit**

The toolkit linked <u>here</u> is provided by the U.S. Department of Health and Human Services. The tools include information about monoclonal antibody treatments, product availability, treatment site resources, payment/allocation, and much more.

#### **Therapy Updates:**

- Veklury (remdesivir) for hospitalized patients, prior to October 2020 allocations were made to the states by HHS. After 2020 it was deemed that there was enough supply to meet demands and the hospitals have the ability to order directly from the distributor. AmeriSource Bergen is the sole distributor of this drug and it should be administered according to the EUA. For additional information about the drug the hospitals can email remdesivir@amerisourcebergen.com or call 1-800-746-6273, or reach out directly to their AmeriSource Bergen representative.
- **Bamlanivimab** a monoclonal antibody therapy for non-hospitalized patients. This therapy is currently on pause and not available for ordering. As of June 25, 2021, the distribution of the combination bamlanivimab/etesivimab has been paused nationally until further notice.
- REGEN-COV a monoclonal antibody therapy available for use in Illinois for nonhospitalized patients. Combination of two drugs, casirivimab and imdevimab Currently authorized and available for direct <u>ordering</u> through AmeriSource Bergen. Can be given <u>Intravenously (IV)</u> but has also been authorized for <u>Subcutaneous injection</u> (SubQ) via 4 subQ injections if that is the only mechanism for administration is available. Can access the monoclonal antibody playbook <u>here</u> for steps to perform the infusion process from start to finish.
- Actemra (tocilizumab) is currently used to treat very sick COVID patients for hospitalized patients. The drug is not held by SNS. It is in very tight supply now that an EUA has been granted for treatment of COVID and the manufacturer Genentech has moved it to an all-drop-shipment model, which enables Genentech to can have tighter control over allocation. There is currently a shortage of this drug as explained in the August 16<sup>th</sup> Press Release from Genentech. Potential alternative treatments to consider would include dexamethasone, Remdesivir, and baracitinib (Olumiant). Hospitals should remain engaged with their drug wholesaler on supply and access and major distributors are working closely with Genentech on this issue.

#### Additional contacts:

IDPH technical assistance contact for monoclonal antibody therapy <u>ashley.thoele@illinois.gov</u>. Therapeutic Questions: Please contact <u>COVID19Therapeutics@hhs.gov</u>. AmeriSource Bergen: <u>C19therapies@amerisourcebergen.com</u> REGEN-COV Direct Ordering Process <u>link</u> <u>Sotrovimab Direct Ordering Process via GlaxoSmithKline's website</u>

#### Are you registered in SIREN?

SIREN is the state's Health Alert Network that provides tools and capacity for rapid, reliable, and secure web-based alerting. SIREN is the emergency planning, alerting, and notification system for IDPH.

Please use this link to guide you to the correct registration instructions for your public health related classification: <u>http://www.dph.illinois.gov/siren</u>