

### JB Pritzker, Governor

# COVID-19

Ngozi O. Ezike, MD, Director

11/16/2020

## **MEMORANDUM**

- TO: Hospital Administrators Hospital Pharmacists Hospital Emergency Response Coordinators Regional Hospital Coordinating Centers
- FROM: Ngozi O. Ezike, MD Director
- RE: Emergency Use Authorization and Allocations of bamlanivimab

On Friday, November 6, the Assistant Secretary for Preparedness and Response (ASPR) notified health care stakeholders nationwide of the impending emergency use authorization on Eli Lilly's monoclonal antibody treatment for patients diagnosed with COVID-19.

The <u>Lilly Bamlanivimab Antibody Playbook</u> can assist in operationalizing the administration of these antibodies and includes the planning, implementation, and administration considerations as well as useful resources specific to COVID 19. The information and resources included are meant to supplement and not supersede any local requirements for infusion sites of care and healthcare systems should continue to follow local guidelines outlined for infusion administration.

#### <u>Overview</u>

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product bamlanivimab for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

High risk is defined as patients meeting at least one of the following criteria and the Playbook provides guidance for those meeting certain criteria including, but not limited to the following:

- Have a body mass index (BMI) greater than 35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are 65 years of age or older

There are limitations to the use of this monoclonal antibody treatment. Bamlanivimab is not authorized for use in patients:

- who are hospitalized due to COVID-19, OR
- who require oxygen therapy due to COVID-19, OR
- who 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.

The intended administration setting for the infusion is an outpatient setting over 1 hour with at least an additional hour of observation upon completion. Health systems are asked to determine optimal locations also know as "infusion sites of care" for administering this treatment to outpatients, considering all the precautions and personal protective equipment (PPE) requirements in managing patients with COVID-19 infection. The playbook outlines the requirements for infusion sites that addresses the preparation, storage, and handling of bamlanivimab and recommendations for emergency medical equipment necessary to monitor patients during infusions.

#### **Allocations**

Allocations occur weekly and will closely mirror the most recent process outlined by the Illinois Department of Public Health for remdesivir. A predetermined allocation will be made from the federal government to the Illinois Department of Public who will then allocate to hospitals. Amerisource Bergen will distribute the product to the hospitals. Initially, the donated product will be offered to hospitals and health systems only. As supplies and infrastructure improves, there is potential for the treatment to be offered at other outpatient localities, provided appropriate precautions can be taken. State <u>allocations</u> will be posted on the ASPR phe.gov website. The state allocations are based on a weighted average of the 7-day confirmed hospitalization data set hospitals submit to HHS protect along with total burden of case counts within a jurisdiction as is submitted by state departments of health.

Allocations may be shared amongst hospitals in health systems. Any vials of bamlanivimab that are not accepted by a hospital will be re-allocated to other hospitals based on urgent requests to IDPH.

Week 1 allocations will occur the week of November 17, 2020 and IDPH has been allocated 6,380 vials of bamlanivimab. One vial equals one treatment course. The following methodology was used to calculate the allocations to health systems:

- Prioritization of Safety Net Hospitals and Regional Hospital Coordinating Centers in each Public Health Region
- Consideration for the proportion of Med/Surg and ICU bed usage by COVID patients for the week of November 4, 2020 November 10, 2020.
- Those hospitals that completed the Capability Assessment survey and indicated the capability and plans for administration of bamlanivimab.

#### **Supportive Resources**

Questions regarding the allocation process and methodology should be directed to <u>ashley.thoele@illinois.gov</u>.

Questions regarding the bamlanivimab distribution process from Amerisource Bergen should be directed to their customer support by calling 1-800-746-6273, or by reaching out directly to your Amerisource Bergen representative.

CMS has provided resources on billing for donated therapeutic on the agency's website. The <u>FAQ</u> document for COVID-19 Medicare Fee-For-Service(FFS) Billing. Information regarding hospital outpatient billing of EUA products can be found on page 121 of the linked document.

Find more information about monoclonal antibody drugs and vaccines from the CDC, State Health Departments, and the following resources:

- <u>www.coronaviruspreventionnetwork.org</u>
- <u>www.infusioncenter.org/</u>
- <u>Fact Sheet for Healthcare Providers</u>
- Fact Sheet for Patients, Parents and Caregivers (English)
- Fact Sheet for Patients, Parents and Caregivers (Spanish)
- FDA Letter of Authorization

# Bamlanivimab Allocations Week of 11/13/20

Hospitals	# of Vials
Region 1	
JAVON BEA HOSPITAL: RIVERSIDE CAMPUS	75
SWEDISH AMERICAN HOSPITAL	135
OSF ST. ANTHONY MEDICAL CENTER	75
CGH MEDICAL CENTER	50
FHN MEMORIAL HOSPITAL	40
NW MEDICINE KISHWAUKEE HOSPITAL	30
KATHERINE SHAW BETHEA HOSPITAL	20
Region02	
OSF ST. ELIZABETH MEDICAL CENTER	20
OSF ST. FRANCIS MEDICAL CENTER	160
UNITYPOINT HEALTH - TRINITY ROCK ISLAND	65
UNITYPOINT HEALTH - METHODIST	45
OSF ST. JOSEPH MEDICAL CENTER	30
OSF ST. MARY MEDICAL CENTER	25
GENESIS MEDICAL CENTER, SILVIS	25
CARLE BROMENN MEDICAL CENTER	35
ST. MARGARETS HOSPITAL	20
GALESBURG COTTAGE HOSPITAL	20
OSF ST. JAMES HOSPITAL	20
MCDONOUGH DISTRICT HOSPITAL	20
Region03	
BLESSING HOSPITAL AT 11TH STREET	95
MEMORIAL MEDICAL CENTER (SPRINGFIELD)	90
HSHS ST. JOHNS HOSPITAL	100
PASSAVANT AREA HOSPITAL	20
MEMORIAL HOSPITAL (CARTHAGE)	20
Region04	
GATEWAY REGIONAL MEDICAL CENTER	20
TOUCHETTE REGIONAL HOSPITAL	20
HSHS ST ELIZABETH'S HOSPITAL, O'FALLON	45
MEMORIAL HOSPITAL (BELLEVILLE)	95
ANDERSON HOSPITAL	30
ALTON MEMORIAL HOSPITAL	20
SSM HEALTH ST. MARY'S HOSP. (CENTRALIA)	20
HARRISBURG MEDICAL CENTER	20

SSM HEALTH GOOD SAMARITAN HOSPITAL	30
SIH HERRIN HOSPITAL	30
SIH MEMORIAL HOSPITAL OF CARBONDALE	100
Region06	
CARLE FOUNDATION HOSPITAL	80
DECATUR MEMORIAL HOSPITAL	55
SARAH BUSH LINCOLN HEALTH CENTER	50
HSHS ST. MARYS HOSPITAL (DECATUR)	30
HSHS ST. ANTHONYS MEMORIAL HOSPITAL	20
OSF HEART OF MARY MEDICAL CENTER	20
OSF SAINT ANTHONY'S HEALTH CTR (ALTON)	20
Region07	
ADVOCATE CHRIST MEDICAL CENTER	190
PALOS COMMUNITY HOSPITAL	150
AMITA HEALTH SAINT JOSEPH MEDICAL	445
CENTER OSF LITTLE COMPANY OF MARY MEDICAL CTR	115
FRANCISCAN HEALTH?OLYMPIA FIELDS	100
ADVOCATE SOUTH SUBURBAN HOSPITAL	90
INGALLS MEMORIAL HOSPITAL	55
RIVERSIDE MEDICAL CENTER	55
MORRIS HOSPITAL	50
OSF SACRED HEART MEDICAL CENTER	25
AMITA HEALTH ST. MARY'S HOSPITAL	25
Pagian08	20
Region08           AMITA HEALTH ADVENTIST GLENOAKS	
HOSPITAL	40
WEST SUBURBAN MEDICAL CENTER	25
ELMHURST HEALTH: EDWARD HOSPITAL	120
ELMHURST HEALTH: ELMHURST HOSPITAL	110
NW MEDICINE CENTRAL DUPAGE HOSPITAL	110
MACNEAL HOSPITAL	95
LOYOLA UNIVERSITY MEDICAL CENTER	85
ADVOCATE GOOD SAMARITAN HOSPITAL	70
GOTTLIEB MEMORIAL HOSPITAL	50
AMITA HEALTH ADVENTIST BOLINGBROOK HOSP.	45
AMITA HEALTH ADVENTIST LAGRANGE	
HOSPITAL AMITA HEALTH ADVENTIST HINSDALE	45
HOSPITAL	40
RUSH OAK PARK HOSPITAL	30

Region09	
AMITA HEALTH MERCY MEDICAL CENTER	65
ST. ALEXIUS MEDICAL CENTER	145
ADVOCATE LUTHERAN GENERAL HOSPITAL	135
ALEXIAN BROTHERS MEDICAL CENTER	120
NORTHWEST COMMUNITY HOSPITAL	115
ADVOCATE SHERMAN HOSPITAL	85
RUSH COPLEY MEDICAL CENTER	75
NORTHWESTERN MEDICINE MCHENRY HOSPITAL	55
NORTHWESTERN MEDICINE HUNTLEY	50
HOSPITAL NORTHWESTERN MEDICINE DELNOR HOSPITAL	<u> </u>
ADVOCATE GOOD SHEPHERD HOSPITAL	40
AMITA HEALTH ST. JOSEPH HOSPITAL - ELGIN	30
Region10	
VISTA MEDICAL CENTER EAST	85
ADVOCATE CONDELL MEDICAL CENTER	120
NORTHWESTERN MEDICINE LAKE FOREST HOSP.	55
AMITA HEALTH ST. FRANCIS HOSPITAL	55
Region11	
AMITA SAINTS MARY & ELIZABETH MED	
CENTER SWEDISH HOSPITAL	95
MOUNT SINAI HOSPITAL	80
HOLY CROSS HOSPITAL	50
ANN & ROBERT H LURIE CHILDREN'S HOSPITAL	50
SAINT ANTHONY HOSPITAL	40
NORWEGIAN AMERICAN HOSPITAL	30
SAINT BERNARD HOSPITAL	30
JACKSON PARK HOSPITAL & MEDICAL CENTER	25
SOUTH SHORE HOSPITAL	20
ROSELAND COMMUNITY HOSPITAL	20
THOREK MEMORIAL HOSPITAL	20
METHODIST HOSPITAL OF CHICAGO	20
NORTHWESTERN MEMORIAL HOSPITAL	20
JOHN H. STROGER JR. HOSPITAL COOK	140
COUNTY UNIVERSITY OF CHICAGO MEDICAL CENTER	100
AMITA RESURRECTION MEDICAL CTR CHICAGO	90
RUSH UNIVERSITY MEDICAL CENTER	90
	185

UNIVERSITY OF ILLINOIS HOSPITAL & HSS	75
COMMUNITY FIRST MEDICAL CENTER	55
ADVOCATE TRINITY HOSPITAL	50
ADVOCATE ILLINOIS MASONIC MEDICAL	
CENTER	50
AMITA SAINT JOSEPH HOSPITAL CHICAGO	40
WEISS MEMORIAL HOSPITAL	25
COMER CHILDREN'S HOSPITAL	20
Total Vials	6380