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Guidance for the Emergency Use Authorization of Eli Lilly and Company's bamlanivimab and Regeneron's casirivimab/imdevimab

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. Shortly thereafter, an additional antibody therapy by Regeneron called casirivimab/imdevimab, which is an antibody cocktail formulated from two different medications was made available.

Overview

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 and the antibody cocktail casirivimab/imdevimab 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. Antibody therapies such as bamlanivimab and casirivimab/imdevimab are likely to be most effective when given early in infection and the product is delivered via a single intravenous infusion.

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 and casirivimab/imdevimab are 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 Lilly Bamlanivimab Antibody Playbook can assist in operationalizing the administration of these bamlanivimab. Information about the administration of

Regeneron'scasirivimab/imdevimab can be found here. Additionally, Operation Warp Speed has developed an OWS Therapeutics: Monoclonal Antibody Playbook for outpatient administration. These resources include 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.

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 Health who will then allocate to hospitals and qualifying outpatient facilities. Amerisource Bergen will distribute the product to the appropriate medical facilities. In phase 1 of distribution the donated product will be offered to hospitals and health systems only and as supplies and infrastructure improves, phase 2 does allow for bamlanivimab to be offered at other outpatient localities, provided appropriate precautions can be taken. State allocations 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 and other outpatient providers within a health system, but allocations must remain in Illinois. Hospitals may further choose to partner with infusion care sites such as medical groups or independently owned infusion centers. All hospitals should follow internal policies and procedures for medication chain of custody and ensure all partners follow Emergency Use Authorization guidelines. To ensure fair and equitable administration of bamlanivimab, hospitals should consider collaborating with medical groups, physician practices, and infusion centers, whether within the health system or independently owned, as the recipient of the drug allocation when that partner serves high priority populations, including aged, Latino, Black, and rural communities.

Strategic Planning for Administration

Health systems are asked to determine optimal locations also known 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. Health care facilities should work in partnership with other infusion care sites if necessary. This should include preparing the site for administration and developing procedures to identify and treat patients in a timely manner. Infusion sites should prepare for scheduling and routing of referrals from testing centers or other healthcare providers to treatment.

The playbook outlines the requirements for infusion sites that addresses the preparation, storage, and handling of bamlanivimab and casirivimab/imdevimab. The intended administration setting for the infusion is an outpatient setting over 1 hour with at least an additional hour of observation upon completion.

As outlined by the EUA, infusion care sites shall have standard operating procedures in place instructing the infusion care site staff how emergency events should be managed that include appropriate emergency contacts for physicians and 911 response services. Infusion care sites should also follow policies and protocols for the use of essential emergency equipment and supplies as outlined in the EUA and antibody playbook. Some medications listed in the playbook should only be administered by healthcare personnel with Advanced Cardiac Life Support (ACLS) training.

Patients receiving antibody therapy should be informed that the EUA issued is for investigational treatment but does not constitute research on behalf of the hospital or infusion site. All measures to ensure patient privacy (HIPAA compliant) should be maintained during the infusion process.

Supportive Resources

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

Questions regarding the bamlanivimab and casirivimab/imdevimab 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 or by emailing c19therapies@amerisourcebergen.com.

CMS has provided resources on billing for donated therapeutic on the agency's website. There is also an FAQ 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:

- www.coronaviruspreventionnetwork.org
- www.infusioncenter.org/
- ASPR's COVID-19 Medical Countermeasures