Tom Muldrow presentation notes, January 7, 2021

As a part of US government's effort in advancing therapeutics to "attack the virus," neutralizing monoclonal antibodies (mAbs) have been given an Emergency Use Authorization (EUA) based on their ability to:

- Decrease viral load
- Reduce likelihood of disease progression & hospitalization

The 2 available EUA approved mAb products are as following:

- Bamlanivimab (Eli Lilly)
- Casirivimab& Imdevimab (Regeneron)

Both EUAs - Non-hospitalized patients with mild to moderate symptoms with less than 10 days since symptom onset & high-risk factors incl.:

- Age >65 years, or >55 years and 12-17 years with
- Obesity with BMI >35 (adults)
- High risk conditions including diabetes, chronic kidney disease, coronary artery disease, hypertension and others

To be administered by professional personnel and requires 1-hour of infusion time and 1-hour post-infusion observation

Federal allocation decision for both drugs informed by two data sources provided by hospitals/health departments to HHSProtect

1. *Confirmed Hospitalizations (7-Day Incident)*
2. *Confirmed Cases (7-Day Incident)*

Phase 1: states and territories allocate to hospitals and hospital affiliated locations only

Phase 2: states and territories can allocate to additional outpatient facilities

- Allocation of bamlanivimab is in Phase 2
- Allocation of casirivimab/imdevimab is now in Phase 2

Project SPEED. The Special Projects for Equitable and Efficient Distribution (SPEED) program is a federal monoclonal antibody (mAb) allocation program that is separate from the state-based allocation system.

Total bamlanivimab and casirivimab/imdevimab allocated to Ohio (delivered to treatment facilities): 24,940 patient courses (a/o Dec 31)

- 19,750 patient courses - Eli Lilly (cycle 7)

5,190 patient courses - Regeneron (cycle 5)

Allocations of therapeutics were made by the federal government for delivery of medications to all 50 states and territories, the Veterans Health Administration, and the Indian Health Service. To inform OWS allocations, Ohio refined the process initially used to allocate and distribute the antiviral drug remdesivir. The first OWS allotments for Ohio have arrived, and — in consultation with a team of clinicians, pharmacists, public health officials, policymakers, and other health experts — the state has identified a clinically based plan for current and future allotments. This plan will be put in place as drug production ramps up and clinical trials and other work to fulfill requirements for full FDA approval is completed. Ohio's multidisciplinary consulting group will monitor the evolving science on emerging therapeutics in the same way it did with remdesivir and modify recommendations as needed.

Within each of the state's three hospital zones, allocations to specific hospitals will be determined based on the percentage of COVID-19 patients hospitalized (using seven-day incident data), which is consistent with the federal allocation strategy

I wanted to provide you with an update on Project SPEED. The Special Projects for Equitable and Efficient Distribution (SPEED) program is a federal monoclonal antibody (mAb) allocation program that is separate from the state-based allocation system. SPEED is focused on providing mAbs to four priority populations/settings: LTC facilities, FQHCs, dialysis centers, and correctional facilities. During SPEED Cycle 1 (Dec 16-22), therapeutic allocations were approved for 18 long term care pharmacies in Ohio.

If one of the hospitals in your zone is contacted by a nursing home, and are unable to support, they can redirect them to their associated LTC pharmacy. The federal effort is being coordinated on the Long Term Care Pharmacy side by the American Society of Consultant Pharmacists with new pharmacies being added daily. Pharmacies who would like to participate can email Chad Worz with the American Society of Consultant Pharmacists at cworz@ascp.com. There is also additional information available on their website: https://www.ascp.com/page/mab

Chad Worz, PharmD, BCGP
Chief Executive
cworz@ascp.com
703.739.1301