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Special Bulletin

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UPDATE: Operation Warp Speed Playbook for Allocation and Distribution of COVID-19 Therapeutic Medications

In anticipation of the likely issuance of emergency use authorizations (EUAs) for at least two monoclonal antibody therapeutic drugs developed to treat certain COVID-19 positive patients, Operation Warp Speed released an initial playbook to assist providers in planning. The playbook lays out important information for hospitals and health systems to consider.

Please note the playbook is still in draft form; it therefore will continue to evolve as more information becomes available. In particular, specifics about which patients are to receive this therapy likely will be provided as part of the Food and Drug Administration's EUA. Hospitals should be prepared for these specifications to potentially narrow the pool of eligible patients.

Briefly, the playbook includes the information on the following:

Administration. These monoclonal antibody therapeutic drugs are administered by infusion in an outpatient setting to patients at elevated risk of severe outcomes from COVID-19.

Two Therapeutic Options. The Eli Lilly product has shown potential to reduce hospitalization; the Regeneron product has shown potential to reduce viral load, compared to placebo.

Patient Candidates. Both products could be authorized for emergency use in mild-to-moderate COVID-19 cases when:

- there is a positive polymerise chain reaction (PCR) or antigen test;
- it is early in the illness' progression; and
- the individual has not yet required hospitalization

Initially, while the drugs are in short supply, the treatments may be reserved for high-risk patients over the age of 65. Those individuals receiving the infusion should do so within three days of a positive test and within 10 day of symptom onset.

Site Checklist. Due to outpatient infusion requirements associated with the monoclonal antibody treatments, providers will need to navigate a series of potential challenges at

the point of administration. The playbook provides a comprehensive checklist and a series of considerations that should be taken into account in order to safely and effectively administer the drugs. Some of those considerations include:

- personal protective equipment (PPE) and supply requirements;
- dedicated space to manage patient flow;
- personnel requirements; and
- drug storage and administration requirements.

Distribution and Shipping Information. Distribution of both therapeutics will be overseen by the federal government and managed by Amerisource Bergen. Each product will need to be shipped and stored at a refrigerated temperature of 2-8 degrees Celsius and will have a shelf-life of at least 10 months. *Please note that prepared solutions are meant for immediate administration.*

The AHA will continue to send out further updates on this process as more information becomes available.

Further Questions
If you have questions, please contact AHA at 800-424-4301.