

October 30, 2020

## Preparing 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, providers should begin planning for the distribution and administration process of these therapeutics. The following information is intended to assist hospitals and health systems as they begin discussing how to prepare their facilities and staff.

**Distribution.** The medications initially will be in short supply due to the need to increase production rapidly following the issuance of EUAs. To ensure appropriate allocation while supply remains limited, the federal government will employ an allocation process similar to the one used for Remdesivir.

The process will play out as follows:

- drug manufacturers notify the federal government of supplies available for a week;
- the federal government notifies each state of its allocation, which is based on data from hospitals' daily reporting and other public health data already being collected;
- each state informs the federal government of health care delivery sites to which its allocation is to be delivered; and
- hospitals, and potentially other sites, receive, store and administer their allotment based on guidelines currently in development by the National Institutes of Health, as well as facility-specific criteria.

**Administration.** At least initially, providers should expect any EUA for monoclonal antibody therapeutic drugs to allow for their administration in *ambulatory settings*. The drugs will be administered to patients through an infusion process that lasts at least one hour. After the drug's administration is complete, patients should remain at the administration site for a short period of time to ensure there is no hypersensitivity reaction.

**Patients.** The monoclonal antibodies are to be administered only to patients who test positive for COVID-19. In those instances, the drug should be administered within 72 hours of symptoms' onset and before patients require hospitalization. It is expected that in all likelihood, at least for the early stages of distribution, the therapeutics will be designated for those individuals most at risk, particularly individuals over the age of 60 and those with underlying health conditions that place them at higher risk of serious illness. As supply increases, the drugs likely will be made available to more patients.

**What You Can Do.** The AHA advises members to consider the following steps as they begin preparing:

- ✓ Begin making decisions about locations where the therapeutic drugs can be administered in an ambulatory setting.
- ✓ Consider how these sites would be staffed and what resources would be needed on site.
- ✓ Consider what actions need to be taken to ensure safety from COVID-19 exposure for health care staff, as well as non-COVID-19 patients.
- ✓ Given their higher proportion of at-risk patients, post-acute care providers should expect to play a role in the administration of these drugs.

The AHA will continue to send out updates on this process as more information becomes available. In addition, once sufficient information is available, the AHA will supply members with a playbook detailing steps to take regarding the therapeutics' receipt, storage and administration.

### **Further Questions**

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