January 25, 2022

Dear Healthcare Partners,

The U.S. Health and Human Services Assistant Secretary for Preparedness and Response (ASPR) announced yesterday that due to the Omicron variant being the dominant variant circulating within the United States, the allocation and distribution of two COVID-19 monoclonal antibody products, bamlanivimab/etesevimab and casirivimab/imdevimab, will be paused indefinitely effective January 24, 2022 (beginning of allocation Cycle 16). In vitro testing has predicted that these two products have markedly reduced susceptibility and are unlikely to be effective against the Omicron variant. The FDA announced that these two treatments are not currently authorized for use anywhere in the U.S. due to the prevalence of Omicron and the EUAs have been updated with this information. Sotrovimab and Evusheld (tixagevimab/cilgavimab) appear to be effective against the Omicron variant and will be the only COVID-19 monoclonal antibody products available for distribution at this time.

Effective immediately, ADHS will be unable to fulfill any requests of bamlanivimab/etesevimab and casirivimab/imdevimab supply for this and future allocation cycles. ADHS recommends that healthcare facilities pause administration and keep the existing supply of these two products until we receive further guidance from the federal authorities. Given the limited federal supply of sotrovimab, ADHS encourages facilities to determine local prioritization schemes and reserve treatment with sotrovimab for eligible outpatients at highest risk for severe COVID-19. Please refer to the NIH COVID-19 Treatment Guidelines Panel’s Statement on prioritization when there are logistical or supply constraints for more information.

We recommend healthcare providers utilize the COVID-19 Outpatient Therapeutics Decision Guide to assist with clinical decision-making for COVID-19 treatment options. Alternative regimens include the COVID-19 oral antivirals Paxlovid and molnupiravir for outpatients, as well as IV remdesivir. All these have been shown to be effective against the Omicron variant. Please visit the ADHS COVID-19 Antivirals webpage for more information about the oral antivirals. Evusheld may only be utilized for pre-exposure prophylaxis of immunocompromised individuals and is not currently authorized for the treatment of COVID-19 infection.

ADHS strongly encourages your facilities to adhere to the federal reporting requirements of the COVID-19 monoclonal antibody products, as this information greatly influences future supply allocations for the state of Arizona. The federal government determines the weekly distribution amount of mAb products each state and territory receives based on COVID-19 case burden and hospitalizations as well as data on inventories and mAbs use submitted within the respective federal reporting portals. Your facility’s sotrovimab inventory data should be reported weekly into the HHSProtect Portal. If your facility
has been allocated Evusheld, its inventory data should be entered daily into the Health Partner Ordering Portal (HPOP). Please reach out if your facility has questions regarding this federal reporting requirement.

We appreciate your flexibility as we all work through the dynamic challenges associated with the evolving COVID-19 pandemic.

Please send questions to therapies@azdhs.gov.

Sincerely,

ADHS COVID-19 Therapeutics Team

Resources

- Fact Sheet for Providers, Sotrovimab EUA - FDA
- Fact Sheet for Providers, Tixagevimab/cilgavimab EUA - FDA
- Monoclonal Antibody Products for COVID-19 Treatment - ADHS
- Antivirals for COVID-19 Treatment - ADHS
- COVID-19 Outpatient Therapeutics Decision Guide - ADHS