Maryland
DEPARTMENT OF HEALTH

New COVID-19 Therapeutics Update
November 16, 2021

Background

The U.S. Food and Drug Administration (FDA) is anticipated to approve additional COVID-19 therapeutics in the near future that will be available on an outpatient basis. The United States Government (USG) has purchase agreements for molnupiravir and AZD7442 and is anticipated to allocate supply to jurisdictions in a process similar to that used for monoclonal antibody therapy and remdesivir.

Anticipated Therapeutics Overview

The USG will provide these therapeutics at no cost. Sites may charge a fee for administration and/or dispensing similar to other COVID-19 therapeutics. Given the limited supply available at the onset of the program, a limited number of sites will be strategically selected in each jurisdiction, though any qualified provider may order the therapeutics to be picked up from a pharmacy or other partner.

Both products are under review for EUA and jurisdictions are instructed to be prepared for program launch by November 30, 2021.

Molnupiravir

Molnupiravir (Merck) is an oral antiviral treatment intended for use in adult patients at high risk of progression to severe COVID-19 ("high risk" to be defined in EUA). **It is intended for use within 5 days of symptom onset in people with positive COVID-19 tests** and is not intended for use during pregnancy (negative pregnancy test is likely to be required for women of childbearing age rather than attestation). The ability of providers to perform rapid antigen COVID-19 tests will greatly facilitate the timely use of this therapeutic agent when indicated.

The therapeutic will be distributed as 200mg capsules packaged into a 40-count bottle (4 pills 2x day for 5 days) and can be stored at room temperature. It requires a prescription by an authorized provider, including licensed pharmacists eligible under the PREP Act. FDA has announced a Antimicrobial Drugs Advisory Committee (AMDAC) meeting for November 30, 2021 to review the EUA for molnupiravir.

AZD7442

AZD7442 (AstraZeneca) is an IM injection of a long-acting antibody intended as pre-exposure prophylaxis for immunocompromised or immunodeficient patients, or patients not expected to mount a full immune response to the COVID-19 vaccine. It may require re-dosing every 6 months to ensure full benefit. AstraZeneca filed a request for EUA on October 5, 2021.