Limited Therapeutic Options for Outpatient Treatment of COVID-19

Currently, there are limited therapeutic options for the outpatient treatment of COVID-19 infection. Those options include the oral treatments nirmatrelvir/ritonavir (Paxlovid/Pfizer) and molnupiravir (Merck) and the monoclonal antibody products bamlanivimab/etesevimab (Eli Lilly), casirivimab/imdevimab (REGEN-COV/Regeneron), and sotrovimab (Xevudy/GlaxoSmithKline). Additionally, tixagevimab/cilgavimab (Evushield/AstraZeneca) is available for pre-exposure prophylaxis.

Each of these treatment options carry a variety of indications and have extensive risk/benefit profiles for each individual patient. As many of the current infections are suspected to be from the omicron variant of the SARS-CoV-2 virus, Bamlanivimab/etesevimab and Casirivimab/imdevimab may have limited efficacy based on in vitro studies. Sotrovimab is expected to maintain its efficacy and tixagevimab/cilgavimab is authorized only for preexposure prophylaxis.

Currently, the supply of sotrovimab, nirmatrelvir/ritonavir and molnupiravir is limited nationally. The Alabama Department of Public Health (ADPH) does not carry a supply of these medications. These treatments are shipped directly to the providers or pharmacies from the manufacturer and are allocated to each state based on population (oral treatments) or orders placed (monoclonal products).

The current allocation for Paxlovid is very limited and ADPH will be using Federal Pharmacy Partners until the allocation increases and allows additional pharmacies to be added. The initial allocation was received at 39 Walmart stores throughout Alabama, with each store getting 20 patient courses. These locations can be found at http://www.walmart.com/covidmedication. The next limited allocation should be received the week of January 10. These same stores will also receive the initial allocation of molnupiravir with a delivery date unannounced but expected soon. Supplies are expected to increase over the coming weeks to months.

Pharmacists interested in dispensing Paxlovid and/or molnupiravir should send the following information to pharmacy@adph.state.al.us:

- Name, address, and phone number of pharmacy
- Name, phone number, and email address of point of contact
- Capacity

We encourage pharmacists to become thoroughly familiar with the fact sheets, links provided below of both products. There are significant counseling requirements and drug interactions that

should be noted before the medications are prescribed or dispensed. The emergency use authorization does not allow pharmacists to prescribe either product.

Due to the limited supplies, treatments should be prioritized for persons who are moderate to severely immunocompromised and to those at high risk of progression to severe disease, including the risk of hospitalization or death if treatment is not administered. Prescribers are urged to use clinical judgment when considering individual treatment options but need to know that current supply is insufficient to cover all persons falling in the immunocompromised and high risk groups. When supplies are ample, prioritization may be less important. Please visit the links below for more information.

As always, vaccines should be used as primary prevention for COVID-19 infection and/or protection against severe disease, hospitalization, or death related to the infection.

For Additional Information:

https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-patient-prioritization-for-outpatient-therapies/

https://emergency.cdc.gov/han/2021/han00461.asp

FDA Fact Sheets:

Bamlanivimab/etesevimab (Eli Lilly)
https://www.fda.gov/media/145802/download

Casirivimab/imdevimab (REGEN-COV/Regeneron)
https://www.fda.gov/media/145611/download

Sotrovimab (Xevudy/GlaxoSmithKline),
https://www.fda.gov/media/149534/download

Nirmatrelvir/ritonavir (Paxlovid/Pfizer)
https://www.fda.gov/media/155050/download

Molnupiravir (Merck)
https://www.fda.gov/media/155054/download

Tixagevimab/cilgavimab (Evushield/AstraZeneca)
https://www.fda.gov/media/154701/download