Providence St. Joseph Health

SBAR

Update to monoclonal antibody and novel oral antiviral therapies

Situation

Current monoclonal antibody treatments including casirivimab/imdevimab and bamlanivimab/etesevimab are not active against the Omicron variant. Sotrovimab has maintained activity[1].

Two new oral antivirals including molnupiravir (Lagevrio) and nirmatrelvir/ritonavir (Paxlovid) have been approved by the FDA under emergency use authorization.

Background

The CDC has reported a significant increase in the proportion of COVID cases due to the Omicron variant across the United States. Research has suggested insufficient effectiveness of bamlanivimab/etesevimab and casirivimab/imdevimab to treat patients with mild to moderate COVID-19 who are at high risk for progression to severe disease. Conversely, early in vitro data suggest sotrovimab retains activity against the Omicron variant[1].

Two new oral antivirals, molnupiravir and nirmatrelvir/ritonavir, have recently received FDA emergency use authorization for treatment of mild-to-moderate COVID-19 patients who are high risk for progression to severe COVID-19, including hospitalization or death. Nirmatrelvir is a protease inhibitor administered with ritonavir to achieve therapeutic plasma levels. Molnupiravir interferes with viral replication by causing mutations in the viral RNA polymerase. Both drugs have specific considerations: ritonavir in the Paxlovid combination has significant drug interactions and molnupiravir has advisories regarding pregnancy.

Assessment

At this time, the only monoclonal antibody recommended for treatment of COVID-19 is sotrovimab. The allocations of this monoclonal antibody will be significantly limited for the foreseeable future. Departments of Health at the state level may also provide prioritization criteria.

Paxlovid and molnupiravir will also remain in limited supply in the near future. In the case that more than one COVID-19 treatment is available locally, molnupiravir should be considered the last option. Specific information about inclusion and exclusion criteria can be reviewed in the updated PSJH COVID treatment guidelines and in the products FDA EUA Fact Sheets[2,3,4]. Allocations of these agents and local availability will depend on distribution by state Departments of Health.

Recommendation

- PSJH should use only sotrovimab as the preferred monoclonal antibody for treatment of mild to moderate COVID-19 infection in outpatients presenting within 10 days of symptom onset and who are at high risk for progression to severe COVID-19, including hospitalization and death.
- Paxlovid and molnupiravir are currently recommended treatment options for mild to moderate COVID-19 infection in outpatients presenting within 5 days of symptom onset and who are at high risk for progression to severe COVID-19, including hospitalization or death.
- Molnupiravir should only be used when alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate.
- Availability and access to these therapeutics will depend on allocation from state Departments of Health to local pharmacies and further information and communication will be made available at local ministries as inventory arrives.

Please contact either George Diaz (george.diaz@providence.org) or Mariesa Durrant (mariesa.durrant@providence.org) with questions.

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References:

1. Cathcart, Andrea L, et al. The dual function monoclonal antibodies VIR-7831 and VIR-7832 demonstrate potent in vitro and in vivo activity against SARS-CoV-2. bioRxiv 2021.03.09.434607; doi: https://doi.org/10.1101/2021.03.09.434607
2. Sotrovimab Healthcare Provider Fact Sheet
3. Paxlovid Healthcare Provider Fact Sheet
4. Molnupiravir Healthcare Provider Fact Sheet