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HEALTH ALERT NETWORK | HEALTH ADVISORY | December 29, 2021

Monoclonal Antibody and Antiviral Updates

This Health Update provides additional information regarding the use of monoclonal antibodies and additional information about the recently authorized anitvirals, molnupiravir and paxlovid.

On December 27, the North Dakota Department of Health (NDDoH) Laboratory Services Section (LSS) reported 33 of 133 (24.8%) specimens that were whole genome sequenced as confirmed Omicron variants.

Sotrovimab continues to be the only monoclonal antibody showing efficacy for the treatment of mild to moderate disease due to the Omicron variant of SARS-CoV-2. The National Institutes of Health have issued guidance for the use of monoclonal antibodies, including prioritizing patients for outpatient treatment with monoclonal antibodies during disease surges or shortages of therapeutics. In their guidance, the NIH states, "When the Omicron variant represents the majority (e.g., >80%) of infections in a region, it is expected that bamlanivimab plus etesevimab and casirivimab plus imdevimab will not be active for treatment or post-exposure prophylaxis (PEP) of COVID-19. Providers are encouraged to use their professional judgement when treating patients with COVID-19."

In light of the above guidance and in preparation for when Omicron is the most dominant variant within North Dakota, healthcare facilities are strongly encouraged to conserve any existing Sotrovimab supply for utilization at a later date. With that concept in mind, healthcare facilities can administer casirivimab plus imdevimab and bamlanivimab plus etesevimab until additional notice is received that Omicron has been deemed the state's predominant variant (> 80%)

The Food and Drug Administration has recently authorized two new antivirals for therapeutic use in people with mild to moderate COVID-19 disease. Molnupiravir and paxlovid have received emergency use authorization and their indications are briefly outlined here. More information on molnupiravir is available here. More information on paxlovid with ritonavir can be found here.

Molnuprivar is indicated for use in adults 18 years of age or older with a positive SARS-CoV-2 viral test:

- who have mild or moderate COVID-19 disease.
- who are at increased risk for progression to severe disease, hospitalization or death due to COVID-19.
- for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate.

Molnupiravir is **not** authorized:

- for use in patients less than 18 years of age.
- for initiation of treatment in patients requiring hospitalization due to COVID-19. Benefit of treatment with molnupiravir has not been observed in subjects when treatment was initiated after hospitalization due to COVID-19.
- for use for longer than 5 consecutive days.
- for pre-exposure or post-exposure prophylaxis for prevention of COVID-19.
- for use during pregnancy. Advise individuals of childbearing potential to use effective contraception correctly and consistently, as applicable, for the duration of treatment and for 4 days after the last dose of molnupiravir.

- for use during lactation. Breastfeeding is NOT recommended during treatment and for 4 days after the last dose of molnupiravir. A lactating individual may consider interrupting breastfeeding and may consider pumping and discarding breast milk during treatment and for 4 days after the last dose of molnupiravir.

Paxlovid is indicated for

- the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg).
- who are at high risk for progression to severe COVID-19, including hospitalization or death.

Paxlovid is **not** authorized:

- for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19.
- for pre-exposure or post-exposure prophylaxis for prevention of COVID-19.
- for use longer than 5 consecutive days.

Contraindications for the use of paxlovid

- History of clinically significant hypersensitivity reactions to the active ingredients (nirmatrelvir or ritonavir) or any other components.
- Co-administration with drugs highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions.
- Co-administration with potent CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance.

Currently the federal government has continued to allocate bamlanivimab and etesevimab along with Regeneron and sotrovimab to states. The two recently authorized antivirals are also being allocated. The North Dakota Department of Health (NDDoH) is receiving courses of the new antiviral medication and will allocate based on population. Rural areas will have access to molnupiravir and paxlovid for eligible patients via the NDDoH Department Operations Center. The operations center can be reached by calling 701-328-0707.

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