NEW MEXICO Department of Health

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NEW MEXICO HEALTH ALERT NETWORK (HAN) ALERT

Update on Omicron and COVID-19 Therapeutics

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Background:
Current data from the New Mexico Scientific Laboratory Division estimates Omicron prevalence in New Mexico is 60%. NM will essentially have 100% Omicron variant by next week.

Given that bamlanivimab and etesevimab (administered together) and REGEN-COV are ineffective against the Omicron variant, the NMDOH and the New Mexico Medical Advisory Team (MAT) recommend that these two therapies no longer be offered as treatment in NM.

Sotrovimab, which retains activity against the Omicron variant, can still be administered but is in very short supply. This week's federal allocation is 174 doses per week across the state.

FDA updated the Health Care Provider Fact Sheets for bamlanivimab and etesevimab administered together, REGEN-COV, and sotrovimab with specific information regarding expected activity against the Omicron variant (B.1.1.529/BA.1).

All laboratory tests used to discriminate the Omicron variant from other SARS COV 2 infections must be validated and approved by the US FDA for this stated purpose in order to use for patient treatment decisions.

Recommended Pause of Bamlanivimab/Etesevimab and REGN-COV for New Mexico Providers:
Once the Omicron variant represents the majority of infections, it is expected that bamlanivimab/etesevimab and Regen-COV will not be active for treatment or post-exposure prophylaxis of COVID-19. In this setting, the NIH Treatment Guidelines Panel recommends using one of the following options to treat non-hospitalized patients with mild to moderate COVID-19 who are at high risk[1]:

- Sotrovimab 500 mg IV as a single infusion administered as soon as possible and within 10 days of symptoms onset
- Remdesivir 200mg IV on Day 1; then 100 mg once daily on Days 2 and 3. This should be initiated as soon as possible and within 7 days of symptom onset.
- Oral therapeutics (see below)

[1] Statement on Anti-SARS-CoV-2 mAbs and RDV and Omicron | COVID-19 Treatment Guidelines (nih.gov)

Given the current prevalence of the Omicron variant in New Mexico, the NMDOH and the Medical Advisory Team (MAT) recommend that providers no longer prescribe or administer bamlanivimab/etesevimab or REGEN-COV.

Healthcare providers should continue to review the antiviral resistance information in the Healthcare Provider Fact Sheet for each authorized therapeutic for details regarding specific variants and resistance.

Prioritizing patients for Sotrovimab Therapy:
Given high case counts and limited therapeutic options, providers are asked to prioritize patients who are at highest risk for COVID-19 for treatment with Sotrovimab. NMDOH recommends that providers use the OMASS tool (see below) and prioritize patients with a score ≥ 6 for Sotrovimab treatment.

Infusion providers may need to further triage patients due to severe supply shortages. Factors that may be considered in triaging patients: symptom onset date and other health risks that may impact a patient's ability to recover from COVID-19. On Sept. 3, 2021, the National Institutes of Health (NIH) COVID-19 Treatment Guidelines Panel issued guidance outlining clinical prioritization when there is insufficient capacity to meet need for monoclonal antibody[2]. NMDOH recommends a different approach to allocation in scarcity that permits the prioritization of both vaccinated and unvaccinated individuals who are at very high risk of progression to severe COVID-19, even if they are not immunocompromised.

Oral Antiviral and Monoclonal Antibody Screening Score (OMASS)
(Adapted from Mayo Clinic's published Monoclonal Antibody Screening Score)[3]

RISK FACTOR	POINTS
Age 65 years and older	2
BMI 35 kg/m^2 and higher	2
Diabetes mellitus	2
Chronic kidney disease	3
Cardiovascular disease in a patient 55 years and older	2
Chronic respiratory disease in a patient 55 years and older	3
Hypertension in a patient 55 years and older	1
Immunocompromised status	3
Pregnancy*	4
BIPOC (Black, Indigenous, People of Color) status	1

*Molnupiravir is not recommended in pregnancy

[2]National Institutes of Health (NIH). September 3, 2021. The COVID-19 Treatment Guidelines Panel's Statement on the Prioritization of Anti-SARS-CoV-2 Monoclonal Antibodies for the Treatment or Prevention of SARS-CoV-2 Infection When There Are Logistical Constraints. www.covid19treatmentguidelines.nih.gov/therapies/statement-on-the-prioritization-of-anti-sars-cov-2-monoclonal-antibodies/

[3] Minnesota Department of Health; **Ethical Framework for Allocation of Monoclonal Antibodies during the COVID-19 Pandemic**

Oral Therapeutics:
Currently, both Molnupiravir and Paxlovid are available in New Mexico through certain Walgreens locations: Current Participating Pharmacy Locations for Oral Therapeutics | NMDOH - Coronavirus Updates (nmhealth.org). These treatments are authorized by the U.S. Food and Drug Administration (FDA) under an Emergency Use Authorization (EUA) for COVID-19 positive individuals who:

- have mild to moderate symptoms
- do not require hospitalization
- have a risk factor(s) for progression to severe COVID-19, including hospitalization

Treatment must be given within 5 days of developing symptoms. Information on prescribing oral therapeutics is on the NM DOH website: COVID-19 Oral Treatments | NMDOH - Coronavirus Updates (nmhealth.org). Phased eligibility criteria are in place to prioritize patients at highest risk. The state is in phase 1-D of oral therapeutics eligibility.

Currently, patients are eligible for oral medications if they meet the following criteria:

- Positive COVID-19 test *AND*
- Treatment can be started within 5 days or less from symptom onset *AND*
- Must reside in an eligible county (all counties are currently eligible) *AND*
- OMASS score of 6 or greater for Paxlovid (score of 3 or greater for children 12 – 17) *OR*
- OMASS score of 3 or greater for Molnupiravir

Additional Information:
For questions, please contact the New Mexico Department of Health COVID-19 Therapeutics Team at covid.thereaputics@state.nm.us

Information on the authorized products for the treatment of mild-to-moderate coronavirus and other authorized products for treatment or prevention of COVID 19 are available on FDA's Emergency Use Authorization Drugs and Non-Vaccine Biological Products webpage.

From HHS: Side-by-Side Overview of Outpatient Therapies Authorized for Treatment of Mild-Moderate COVID-19 (December 3, 2021)

From Minnesota Department of Health: Ethical Framework for Allocation of Monoclonal Antibodies during the COVID-19 Pandemic (mn.gov)

Medication	Reduction In hospitalization & death	Route	Treatment duration	Weekly statewide supply
Paxlovid	88%	Oral	5 days, Twice a Day	170 courses
Remdesivir	87%	Intravenous	3 days (1-2 hour infusions)	Not under allocation
Sotrovimab	85%	Intravenous	One day, 30 minutes	174 Courses
Molnupiravir	30%	Oral	5 days, Twice a Day	770 courses
BAM/ETE	0%	Intravenous	One day, 30 minutes	No longer in use due to ineffectiveness with Omicron
Regeneron	0%	Intravenous	One day, 1 hour	No longer in use due to ineffectiveness with Omicron

New Mexico Health Alert Network: To register for the New Mexico Health Alert Network, click the following link to go directly to the HAN registration page https://nm.readyop.com/fs/4cjZ/10b2 Please provide all information requested to begin receiving important health alerts and advisories.

EPIDEMIOLOGY AND RESPONSE

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