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NEW MEXICO HEALTH ALERT NETWORK (HAN) ALERT

COVID-19 Therapeutics Update: Sotrovimab Pause & Updated NIH Treatment Guidelines

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Background

COVID-19 therapeutics are important tools to decrease morbidity and mortality associated with COVID-19 disease. The efficacy of COVID-19 therapeutics is dependent on circulating variants. Sotrovimab has been found to have substantially decreased in vitro activity against the Omicron BA.2 sub-variant.

The purpose of this communication is to notify providers that the FDA has revoked the authorization for Sotrovimab as a COVID-19 treatment due to the prevalence of BA.2 sub-variant and to provide an update regarding changes to the NIH treatment guidelines.

Updated NIH Treatment Guidelines: Therapeutic Management of Nonhospitalized Adults with COVID-19

On April 1, 2022, the NIH updated their treatment guidelines for non hospitalized adults with COVID-19.

Preferred therapies in order of preference include: Paxlovid and Remdesivir.
Alternative therapies (in alphabetical order) include: Bebtelovimab and Molnupiravir.

The panel recommends against the use of dexamethasone or other systemic corticosteroids in the absence of another indication. [1]

Sotrovimab No Longer Authorized to Treat COVID-19 in the U.S.

Sotrovimab has been found to have substantially decreased in vitro activity against the Omicron BA.2 subvariant. Please refer to the health care provider fact sheet for a summary of the data.

The FDA revoked the authorization of Sotrovimab as a COVID-19 treatment in all Health and Human Services (HHS) regions. The FDA cited that all HHS regions are now estimated to have a BA.2 sub-variant prevalence greater than 50% according to the CDC Nowcast.[2] The CDC Nowcast is a model that estimates more recent proportions of circulating variants and enables timely public health action.

All providers should immediately cease offering Sotrovimab as a treatment for COVID-19. Providers should not discard unused doses of Sotrovimab. It should be quarantined under proper storage conditions in the event it may be used against future variants.

The state has provided a quick reference guide and treatment decision aid to assist providers in appropriate treatment selection. The state recommends prioritization of Tier 1 & 2 COVID-19 therapeutics (Paxlovid and Remdesivir) for patients at risk of severe COVID-19 disease.

1. Therapeutic Management of Nonhospitalized Adults With COVID-19.www.covid19treatmentguidelines.nih.gov
2. FDA updates Sotrovimab emergency use authorization. https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-sotrovimab-emergency-use-authorization

Prioritization of Highly Effective Therapies

Highly effective therapies (Paxlovid and Remdesivir) should be prioritized for patients at the greatest risk of severe COVID-19 disease. The updated NIH treatment guidelines provide guidance on the prioritization of patients. Please refer to the NIH treatment guidelines for a listing of immunocompromising conditions.

Tier	Risk Group
1	• Immunocompromised individuals who are not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to their underlying conditions, regardless of their vaccine status *or* • Unvaccinated individuals who are at the highest risk of severe disease (anyone aged ≥75 years or anyone aged ≥65 years with additional risk factors)
2	• Unvaccinated individuals who are at risk of severe disease and who are not included in Tier 1 (anyone aged ≥65 years or anyone aged <65 years with clinical risk factors)
3	• Vaccinated individuals who are at high risk of severe disease (anyone aged ≥75 years or anyone aged ≥65 years with clinical risk factors) • Vaccinated individuals who have not received a COVID-19 vaccine booster dose are likely to be at higher risk for severe disease; patients who have not received a booster dose and who are within this tier should be prioritized for treatment.
4	• Vaccinated individuals who are at risk of severe disease (anyone aged ≥65 years or anyone aged <65 with clinical risk factors) • Vaccinated individuals who have not received a COVID-19 vaccine booster dose are likely to be at higher risk for severe disease; patients who have not received a booster dose and who are within this tier should be prioritized for treatment.

Resources for New Mexico Healthcare Systems and Providers
Attachment 1: COVID-19 Quick Reference Guide for Providers

Additional Information

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

During a COVID-19 surge, clinicians should check the inventory status prior to treatment selection. Information regarding participating locations, inventory status, and COVID-19 therapeutics can be found at: https://cv.nmhealth.org/providers/covid-19-oral-therapeutics-information-for-providers/

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

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.

1. Therapeutic Management of Nonhospitalized Adults With COVID-19.www.covid19treatmentguidelines.nih.gov
2. FDA updates Sotrovimab emergency use authorization. https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-sotrovimab-emergency-use-authorization