

March 1, 2022

VIA Email

Mr. Gene Hamilton
America First Legal Foundation
300 Independence Avenue SE
Washington, DC 20003
gene.hamilton@aflegal.org

Dear Mr. Hamilton,

Thank you for your inquiry into the provision of medical care to our most vulnerable populations. Equality in healthcare for all New Mexico's citizens is critically important to the establishment of robust medical system that serves the best interests of our entire state.

The CDC states the following regarding people with certain medical conditions:

Long-standing systemic health and social inequities have put various groups of people at increased risk of getting sick and dying from COVID-19, including many people from certain racial and ethnic minority groups and people with disabilities. Studies have shown people from racial and ethnic minority groups are also dying from COVID-19 at younger ages. People in minority groups are often younger when they develop chronic medical conditions and may be more likely to have more than one condition.

<https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html#MedicalConditionsAdults>

We are writing to let you know that due to increased inventory of COVID-19 therapeutics, New Mexico has discontinued the use of the Oral Antiviral and Monoclonal Antibody Screening Score (OMASS) tool. Please see the New Mexico Health Alert Network (HAN) alert *COVID-19 Therapeutics Update: Patient Eligibility Criteria & New COVID-19 Therapeutic* that was issued on February 16, 2022 for more details.

If you have any additional questions, please contact me at 505-469-7845.

Respectfully



M. Shelley Strong
Assistant General Counsel

Enc. 2/16/2022 *New Mexico Health Alert Network (HAN) alert*



MICHELLE LUJAN GRISHAM
Governor

DAVID R. SCRASE, M.D.
Acting Cabinet Secretary

NEW MEXICO HEALTH ALERT NETWORK (HAN) ALERT
COVID-19 Therapeutics Update: Patient Eligibility Criteria & New COVID-19 Therapeutic
2/16/2022

Background

COVID-19 therapeutics are important tools to decrease morbidity and mortality associated with COVID-19 disease. The purpose of this communication is to provide an update on changes to patient eligibility criteria for COVID-19 therapeutics and to inform clinicians of a newly approved COVID-19 therapeutic.

New COVID-19 Therapeutic: Bebtelovimab

On 2/11/22, the FDA granted an Emergency Use Authorization for a new COVID-19 therapeutic, Bebtelovimab. The medication is a monoclonal antibody and is authorized for the treatment of mild-to-moderate COVID-19 disease for patients aged 12+ and weighing ≥ 40 kg. Bebtelovimab 175 mg is given intravenously over a 30 second infusion. An hour observation period is required after the infusion. This new therapeutic is anticipated to be available the week of February 21st, 2022.

In BLAZE-4, Bebtelovimab has been shown to improve symptoms in patients with mild-to-moderate COVID-19. Additionally, a reduction in SARS-CoV-2 viral load on Day 5 was observed relative to placebo, though the clinical significance of this is not known. The clinical trials were not powered or designed to determine differences in clinical outcomes. According to the FDA, it is reasonable to believe that Bebtelovimab may be effective for the treatment of patients with mild-to-moderate COVID-19 to reduce the risk of progression to hospitalization or death. Bebtelovimab retains activity against currently circulating variants.¹

Patient Eligibility Criteria

Effective 2/16/2022, the Oral Antiviral and Monoclonal Antibody Screening Score (OMASS) tool will no longer be utilized in New Mexico. The tool is no longer necessary as current COVID-19 therapeutics inventory exceeds demand.

Providers should determine patient eligibility by reviewing each medication's individual FDA Emergency Use Authorization. The documents can be found on the FDA's [Emergency Use Authorization Drugs and Non-Vaccine Biological Products webpage](#).

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 for patients at risk of severe COVID-19 disease.

1. Fact Sheet for Healthcare Providers: Emergency Use Authorization for Bebtelovimab. <https://www.fda.gov/media/156152/download>
2. People With Certain Medical Conditions. CDC. <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html#MedicalConditionsAdults>
3. Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Providers. CDC. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html>

Patients at Risk of Severe COVID-19 Disease

- Older adults are more likely to get severely ill from COVID-19. More than 81% of COVID-19 deaths occur in people over age 65. The number of deaths among people over age 65 is 80 times higher than the number of deaths among people aged 18-29.²
- The risk of severe COVID-19 increases as the number of underlying medical conditions increases in a person.
 - For a full list of health conditions that increase risk of severe COVID-19 disease, please visit <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/underlying-evidence-table.html>
 - Some health conditions that increase risk include: Cancer, cerebrovascular disease, chronic kidney disease, chronic lung diseases, chronic liver diseases, cystic fibrosis, diabetes mellitus, down syndrome, heart conditions, HIV, Immunosuppressive medications, mental health disorders, neurologic conditions, obesity/overweight, pregnancy and recent pregnancy, sickle cell disease, smoking (current and former), solid organ or blood stem cell transplantation, substance use disorders, thalassemia, and tuberculosis.³

Resources for New Mexico Healthcare Systems and Providers

Attachment 1: COVID-19 Quick Reference Guide for Providers

Attachment 2: COVID-19 Death Risk Ratio (RR) for Select Age Groups and Comorbid Conditions

Attachment 3: COVID-19 Death Risk Ratio (RR) Increases as Number of Comorbid Conditions Increases

Given the projected limited supply of COVID-19 therapeutics for the next few months, 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/>

Additional Information

For questions, please contact the New Mexico Department of Health COVID-19 Therapeutics Team at covid.thereapeutics@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](#)

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.

COVID THERAPEUTICS

Quick Reference for Prescribers

What therapeutic options are available for COVID positive patients?

Therapeutic	Reduction In hospitalization & death	Route	Treatment Initiation from Symptom Onset	Treatment Duration	Considerations	Preference
Paxlovid (Nirmatrelvir/Ritonavir) 300mg/100mg po BID x 5days	88%	Oral	Within 5 days	5 days	Patients age 12+ and ≥ 40kg Multiple drug interactions Adjust dosing for renal impairment Not recommended in severe hepatic impairment	1st Tier
Remdesivir	87%	IV	Within 7 days	3 days (1-2 hr)	Patients ≥ 3.5kg Renal and hepatic considerations	1st Tier
Sotrovimab	85%	IV	Within 10 days	30 minutes	Patients age 12+ and ≥ 40kg	2nd Tier Reserve use for those whom: Paxlovid & Remdesivir are contraindicated or unavailable Outside treatment window for Paxlovid & Remdesivir
Molnupiravir 200mg 4 tabs po BID x 5 days	30%	Oral	Within 5 days	5 days	Patients age 18+ Not recommended in pregnancy Contraceptive recommendations for males and females.	3rd Tier Utilize when other treatment options are contraindicated or unavailable
Bebtelovimab	Clinical trial not powered or designed to determine difference in clinical outcomes	IV	Within 7 days	1 minute	Patients age 12+ and ≥ 40kg	3rd Tier Utilize when other treatment options are contraindicated or unavailable

Where should I refer a patient for IV treatments (Bebtelovimab, Remdesivir or Sotrovimab)?

Please check cv.nmhealth.org for a list of current providers. Please send a referral or have the patient call ahead of time as appointments may be required and inventory status may change.

How do I prescribe oral therapeutics?

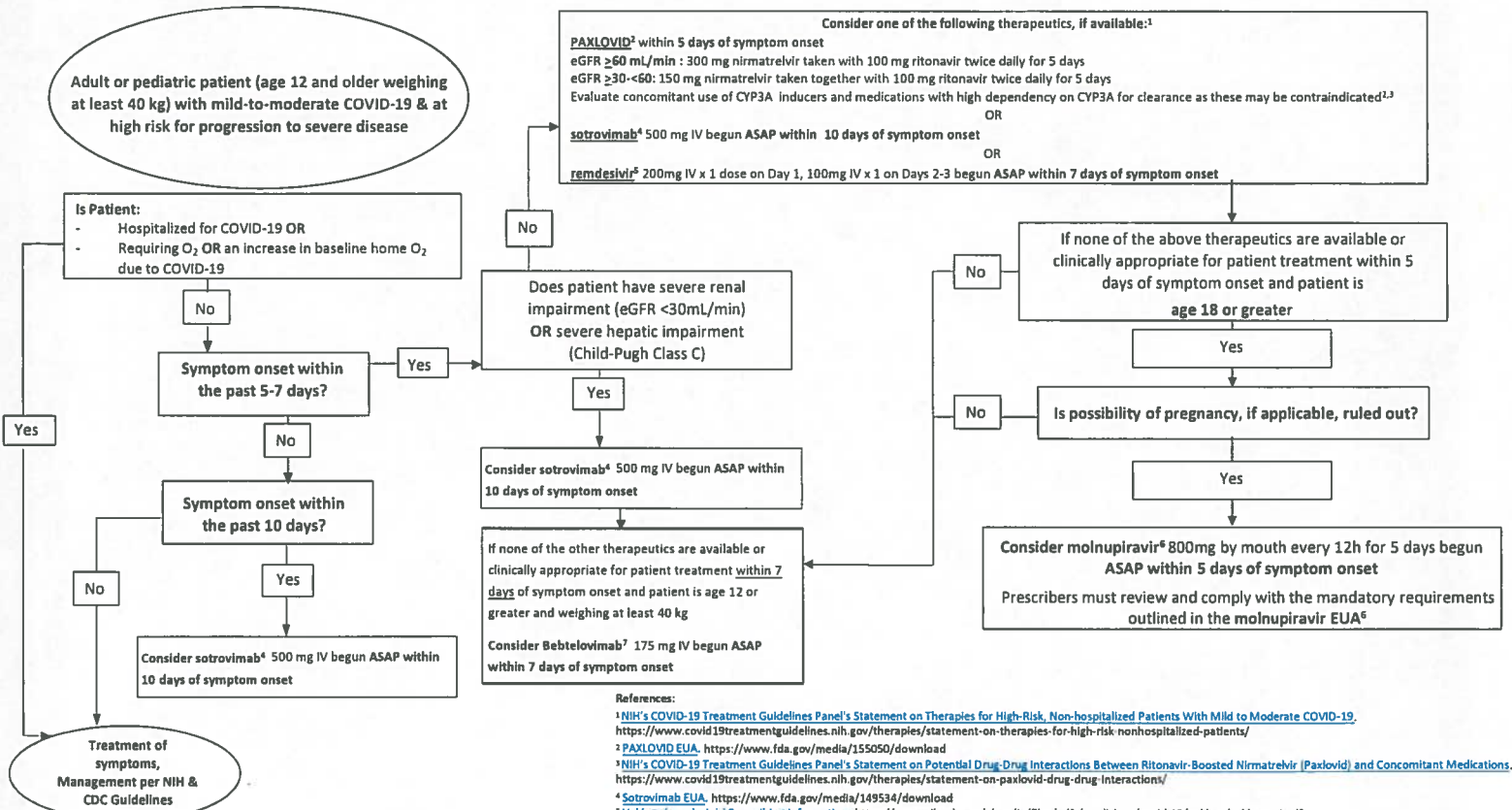
- Please check cv.nmhealth.org for a list of pharmacy locations. Community Walgreens #16544 will overnight medications to a patient's home or preferred pick-up location. Community is open Monday-Friday. Weekend orders after Friday at 4pm must be sent to a drive thru location.
- **Ask patients to go through the drive-thru to minimize exposure to pharmacy staff and customers.**
- Please include date of symptom onset. It helps the pharmacy staff ensure the patient receives the medication within the treatment window.

QUESTIONS? EMAIL COVID.THERAPEUTICS@STATE.NM.US

For more information, visit CV.NMHEALTH.ORG and click on the provider information tab

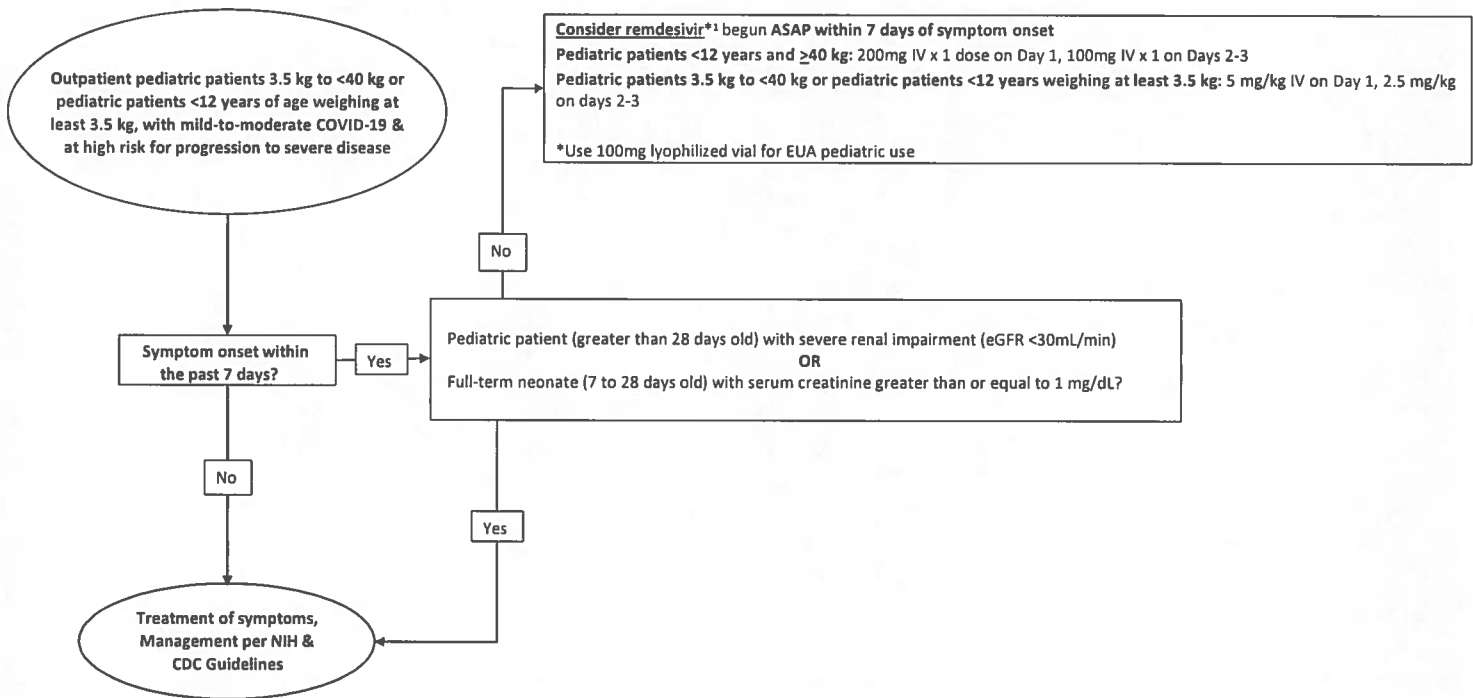


Adult or pediatric patient (age 12 and older weighing at least 40 kg) with mild-to-moderate COVID-19 & at high risk for progression to severe disease

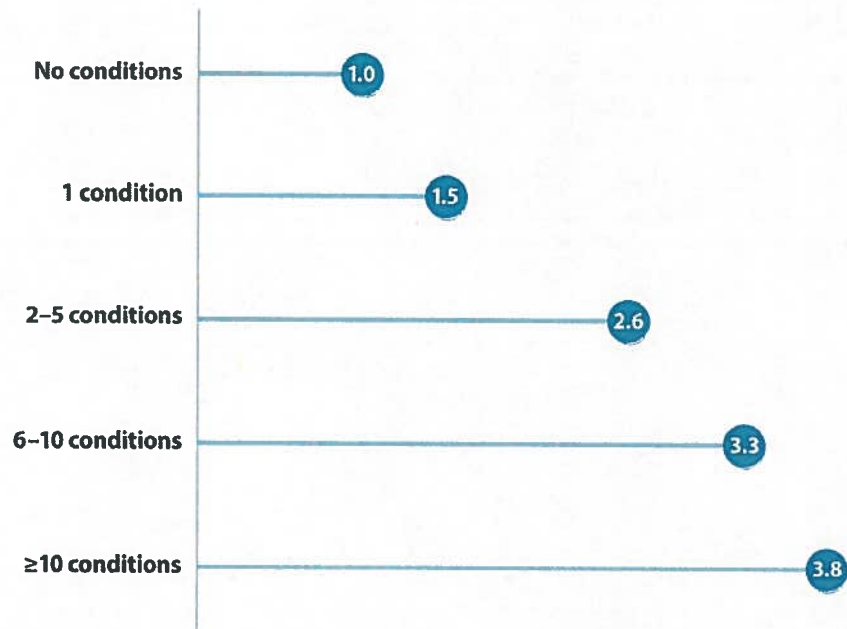


References:

- ¹ NIH's COVID-19 Treatment Guidelines Panel's Statement on Therapies for High-Risk, Non-hospitalized Patients With Mild to Moderate COVID-19. <https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-therapies-for-high-risk-nonhospitalized-patients/>
- ² PAXLOVID EUA. <https://www.fda.gov/media/155050/download>
- ³ NIH's COVID-19 Treatment Guidelines Panel's Statement on Potential Drug-Drug Interactions Between Ritonavir-Boosted Nirmatrelvir (Paxlovid) and Concomitant Medications. <https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-paxlovid-drug-drug-interactions/>
- ⁴ Sotrovimab EUA. <https://www.fda.gov/media/149534/download>
- ⁵ Veklury (remdesivir) Prescribing Information. https://www.gilead.com/-/media/files/pdfs/medicines/covid-19/veklury/veklury_pi.pdf
- ⁶ Molnupiravir EUA. <https://www.fda.gov/media/155054/download>
- ⁷ Bebtelovimab EUA. <https://www.fda.gov/media/156152/download>

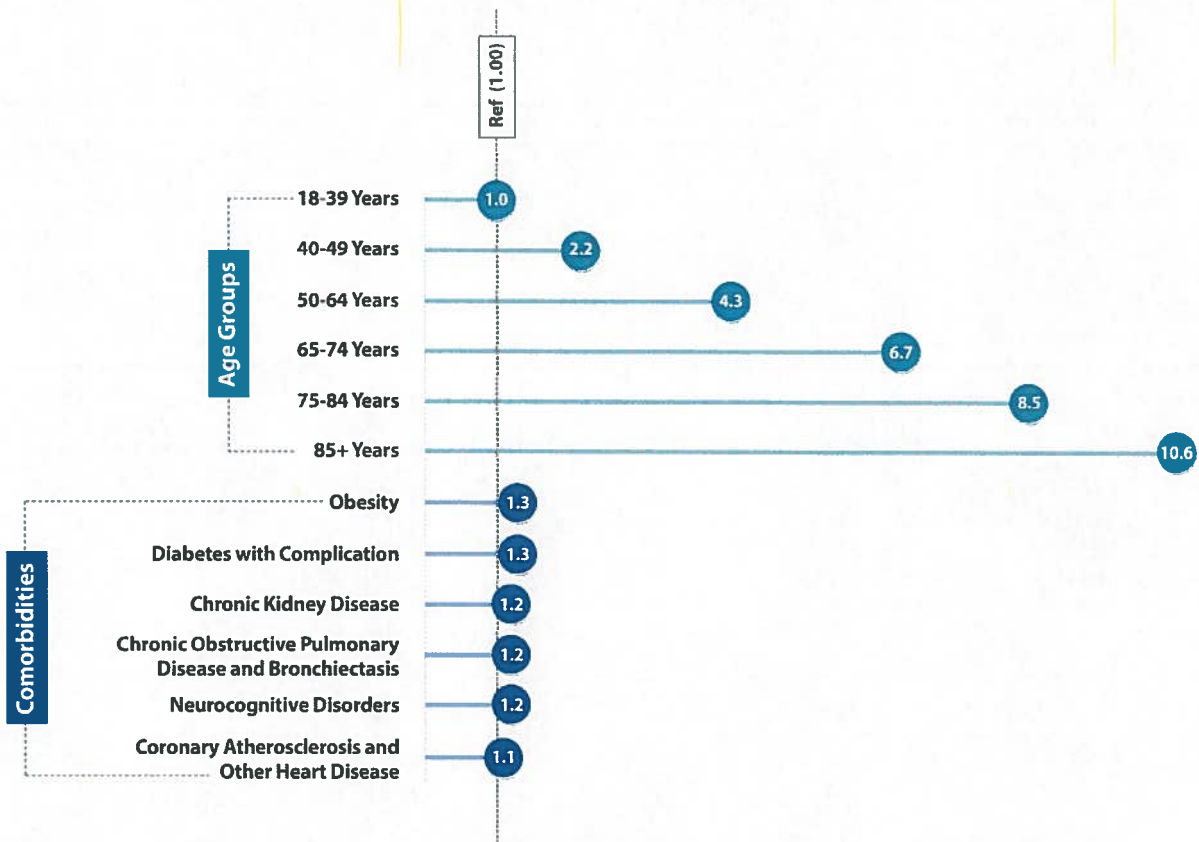


COVID-19 Death Risk Ratio (RR) Increases as the Number of Comorbid Conditions Increases



Source: Kompaniyets L, Pennington AF, Goodman AB, Rosenblum HG, Belay B, Ko JY, et al. Underlying Medical Conditions and Severe Illness Among 540,667 Adults Hospitalized With COVID-19, March 2020–March 2021. To learn more, visit the Preventing Chronic Disease article: https://www.cdc.gov/pcd/issues/2021/21_0123.htm

COVID-19 Death Risk Ratio (RR) for Select Age Groups and Comorbid Conditions



Source: Kompaniyets L, Pennington AF, Goodman AB, Rosenblum HG, Belay B, Ko JY, et al. Underlying Medical Conditions and Severe Illness Among 540,667 Adults Hospitalized With COVID-19, March 2020–March 2021. To learn more, visit the Preventing Chronic Disease article: https://www.cdc.gov/pcd/issues/2021/21_0123.htm