NEW MEXICO Department of Health

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NEW MEXICO HEALTH ALERT NETWORK (HAN) ALERT

COVID-19 Therapeutics Update: Patient Eligibility Criteria & Oral Antiviral & Monoclonal Antibody Screening Score (OMASS)

1/25/2022

Background:

The anti-SARS-CoV-2 therapeutics are important tools to decrease morbidity and mortality associated with COVID-19 disease. The purpose of this communication is to provide clinicians with an update on changes to the Oral Antiviral and Monoclonal Antibody Screening Score (OMASS) tool and to provide a "decision aid tool" for the use of ritonavir-boosted nirmatrelvir (Paxlovid), sotrovimab, remdesivir, and molnupiravir for the treatment of nonhospitalized patients with COVID-19 who are at high risk of progressing to severe disease.

A number of factors affect the selection of the best treatment option for a specific patient. These factors include, but are not limited to, the clinical efficacy of the treatment option, the availability of the treatment option, the feasibility of administering parenteral medications (i.e., sotrovimab, remdesivir), the potential for significant drug-drug interactions (i.e., the interactions associated with using ritonavir-boosted nirmatrelvir [Paxlovid]), renal or hepatic impairment, and pregnancy status.

Updated Patient Eligibility Criteria & OMASS Tool

Due to the limited COVID-19 therapeutic supply, prioritization of patients at greatest risk of progression to severe COVID-19 disease continues to be necessary for all treatment options. However, due to the limited uptake of some therapeutics, the OMASS score requirement is being lowered to facilitate access to and utilization of these therapeutics. This includes the following:

1) Lowering the OMASS scoring threshold for Sotrovimab and Paxlovid from 6 to 3, and Monalpuravir from 3 to 1
2) Including an additional category and OMASS score of 1 for any other underlying medical conditions associated with high risk for severe COVID-19 disease

This change from the Medical Advisory Team is effective 1/25/22.

Updated Guidance for New Mexico Healthcare Systems and Providers:

Changes to COVID-19 Therapeutics patient eligibility criteria and the updated OMASS Scoring Tool are summarized in the following tables. A COVID Therapeutics Decision Aid is also included in this guidance.

Table 1: Updated COVID-19 Therapeutic Patient Eligibility Criteria

Table 2: Updated Oral Antiviral & Monoclonal Antibody Screening Score (OMASS)

Figure 1: COVID-19 Therapeutics Decision Aid Tool[1]

Given the projected limited supply of Paxlovid for the next several months, clinicians should check the inventory status of Paxlovid during treatment selection. The following webpage is updated daily in the afternoon: https://cv.nmhealth.org/providers/covid-19-oral-therapeutics-information-for-providers/

[1] COVID-19 Therapeutics Decision Aid Tool
https://www.phe.gov/emergency/events/COVID19/therapeutics/Documents/COVID-Therapeutics-Decision-Aid.pdf

Table 1: COVID-19 Therapeutic Patient Eligibility Criteria

Therapeutic	Reduction In hospitalization & death	Route	Treatment Initiation from Symptom Onset	Treatment Duration	Weekly Supply (Week 1/24)	OMASS Score Requirement	Preference
Paxlovid	88%[2]	Oral	Within 5 days	5 days	260 courses	Score 3+	**1st Tier**
Remdesivir	87%[3]	IV	Within 7 days	3 days (1-2 hr)	Commercially Available	Score 3+	**1st Tier**
Sotrovimab	85%[4]	IV	Within 10 days	30 minutes	240 courses	Score 3+	**2nd Tier** Reserve use for those whom: ● Paxlovid & Remdesivir are contraindicated or unavailable ● Outside treatment window for Paxlovid & Remdesivir
Molnupiravir	30%[5]	Oral	Within 5 days	5 days	1030 courses	Score 1+	**3rd Tier** ● Utilize only if all other treatment options are unavailable
REGEN-COV	0%[6]	IV	Within 10 days	30 minutes	Not in use	Not in use	Ineffective against Omicron.
BAM/ETE	0%[7]	IV	Within 10 days	1 hour	Not in use	Not in use	Ineffective against Omicron.

[2]FDA FACT SHEET FOR HEALTHCARE PROVIDERS: EMERGENCY USE AUTHORIZATION FOR PAXLOVIDhttps://www.fda.gov/media/155050/download
[3]Gottlieb RL, Vaca CE, Paredes R, et al. Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients. New England Journal of Medicine. December 22, 2021. DOI: https://www.nejm.org/doi/full/10.1056/NEJMoa2116846
[4]FDA FACT SHEET FOR HEALTHCARE PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF SOTROVIMAB https://www.fda.gov/media/149534/download
[5]FDA FACT SHEET FOR HEALTHCARE PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF MOLNUPIRAVIR https://www.fda.gov/media/155054/download
[6]FDA FACT SHEET FOR HEALTHCARE PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF REGEN-COV https://www.fda.gov/media/145611/download
[7]FDA FACT SHEET FOR HEALTHCARE PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF BAMLANIVIMAB AND ETESEVIMAB https://www.fda.gov/media/145802/download

Table 2: Oral Antiviral & Monoclonal Antibody Screening Score (OMASS)

adapted from Mayo Clinic's published Monoclonal Antibody Screening Score (MASS)

RISK FACTOR	POINTS
Age 65 years and older	2
BMI 35 kg/m2 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
Immunosuppressed and unlikely to have responded to vaccines (eg: CD20 inhibitors, BTK inhibitors, campath, recent CAR-T, organ transplant)	3
Pregnancy*,[8]	4
BIPOC (Black, Indigenous, People of Color) status[9]	1
Any other underlying medical condition associated with high risk for severe COVID-19 disease according to the CDC	1

**Molnupiravir is not recommended for use in pregnancy.*

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

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.

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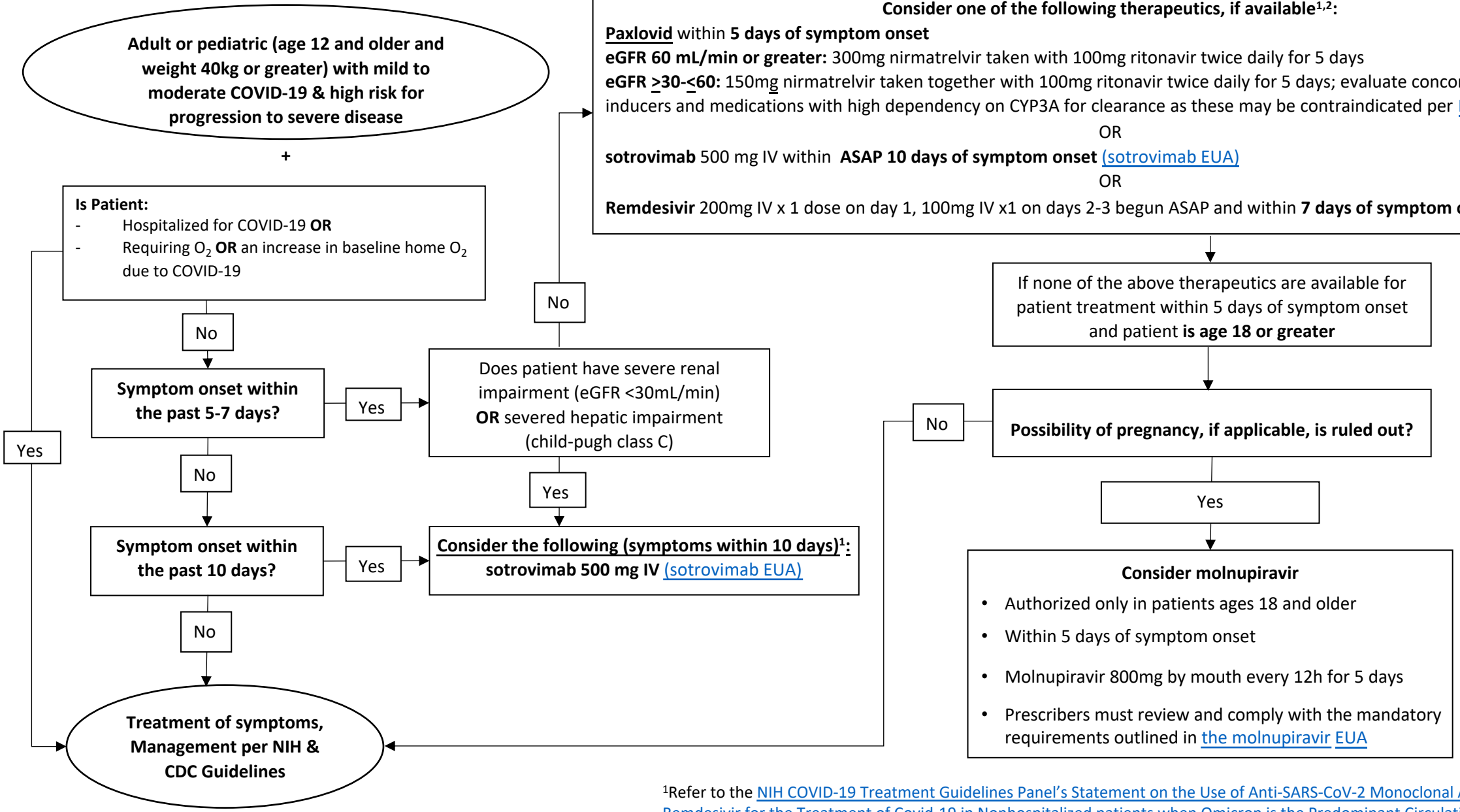
[8] Zambrano LD, Ellington S, Strid P, et al. Update: Characteristics of Sym
ptomatic Women of Reproductive Age with Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status — United States, January 22–October 3, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1641–1647. DOI: http://dx.doi.org/10.15585/mmwr.mm6944e3 external icon.

[9] Wiltz JL, Feehan AK, Molinari NM, et al. Racial and Ethnic Disparities in Receipt of Medications for Treatment of COVID-19 — United States, March 2020–August 2021. MMWR Morb Mortal Wkly Rep 2022;71:96–102. DOI: http://dx.doi.org/10.15585/mmwr.mm7103e1



Limited use of bamlanivimab/etesevimab and REGEN-COV as they are not expected to be active against the Omicron variant[1]

December 30, 2021

[1]Refer to the NIH COVID-19 Treatment Guidelines Panel's Statement on the Use of Anti-SARS-CoV-2 Monoclonal Antibodies or Remdesivir for the Treatment of Covid-19 in Nonhospitalized patients when Omicron is the Predominant Circulating Variant; Remdesivir is only approved for hospitalized individuals with COVID-19. Outpatient treatment is based on information from the literature (Dec 22, 2021 Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients; DOI: 10.1056/NEJMoa2116846)

[2] COVID-19 convalescent plasma with high titers of anti-SARS-CoV-2 antibodies is authorized for the treatment of COVID-19 in patients with immunosuppressive disease in either the outpatient or inpatient setting (COVID-19 Convalescent Plasma EUA)